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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA *ex rel.* FREDERICK D. CURCIO, IV, Plaintiff, v. CCS MEDICAL, INC., DEGC ENTERPRISES (U.S.), INC., and HIGHLAND CAPITAL MANAGEMENT, LP, Defendants.	Case No. **COMPLAINT** **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730** **DEMAND FOR JURY TRIAL**

RELATOR, FREDERICK D. CURCIO, IV'S COMPLAINT PURSUANT TO 31 U.S.C. 3729, *et seq.* OF THE FEDERAL FALSE CLAIMS ACT

The United States of America, by and through *qui tam* relator Frederick D. Curcio, IV and his counsel, bring this action under 31 U.S.C. § 3729 *et seq.*, as amended, to recover all damages, penalties and other remedies established by the False Claims Act on behalf of the United States for violations by the Defendants (*see*, Part II) for knowingly and falsely obtaining and retaining the payment of false claims by the United States in violation of the False Claims Act, 31 U.S.C.§ 3729, *et seq*., as amended by the Fraud Enforcement and Recovery Act of 2009 ("FERA"), 123 Stat. 1617, *et seq.*

I. PRELIMINARY STATEMENT

1. This is an action to recover damages and civil penalties on behalf of the United States of America for violations of the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; and the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812, arising from false or fraudulent records, statements, or claims, or any combination thereof, made, used or caused to be made, used, or presented, or any combination thereof, by the Defendants, together with their current and former shareholders; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them, their agents, employees, or co-conspirators, or any combination thereof, with respect to the Defendants' knowing submission of false claims, and knowing retention of payment from the intentional false claims, which were submitted to the United States Government. On information and belief, Defendants' illegal and unlawful conduct preceded Relator's employment and continues to this day.

2. Defendants knowingly certified, attested, and/or submitted false and fraudulent claims for payment for diabetic, wound care, ostomy and urological products to the United States

Government, as well as several states, including but not limited to the U.S. Department of Health and Human Services – Centers for Medicare and Medicaid Services ("CMS"), which solely administers the Medicare Program and coordinates with the states to administer Medicaid programs, the Department of Defense ("DOD"), which administers the TRICARE program, and the U.S. Department of Veterans Affairs, which administers the CHAMPVA program, and other state and federal governmental agencies and programs (collectively referred to as the "Federal Programs"). Exhibit A contains a complete list of both government and private payors.

3. From at least 2011, Defendants defrauded the U.S. Treasury of over $1 billion when they knowingly and intentionally engaged in a pattern and practice of the following: falsifying patient authorization forms; utilizing a "Just Ship It" mentality, whereby deceased individuals were the intended recipients of diabetic, wound care, ostomy and urological durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") and Medicare and Medicaid beneficiaries often had their copays and/or deductibles waived; shipping more than the monthly allotted amounts of DMEPOS which violated 42 C.F.R. § 424.57, *et seq.*; utilizing a telemarketing scheme, which violated 42 C.F.R. § 424.57(c)(11); and falsely and fraudulently certifying that they had not violated the Social Security Act, Section 1834 (42 U.S.C. § 1395m). Medicare is specifically prohibited from making payment to a supplier that knowingly submits a claim generated pursuant to a prohibited telephone participation, as well as being specifically prohibited from making a payment for materially false claims. These materially false certifications, attestations and submissions and knowing retention of overpayments violated 31 U.S.C. § 3729, *et seq.*, and have caused the United States and the taxpayers financial harm. Accordingly, any and all such claims for payment are false within the meaning of the FCA.

4. In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and

Modernization Act of 2003, Pub. L. 108-183, Section 911 (Dec. 8, 2003) ("MMA 2003"), which authorized the establishment of Medicare Administrative Contractors ("MACs"). MACs have jurisdiction over various multi-state regions located within the United States and its territories. MACs either process Medicare Part A and Part B claims ("A/B") or Durable Medical Equipment claims ("DME"). According to CMS, "[c]urrently, there are 12 A/B MACs and 4 DME MACs in the program that process Medicare [fee for service] claims for nearly 68% of the total Medicare beneficiary population, or 38.5 million Medicare beneficiaries."[1] As of October 2017, Noridian Healthcare Solutions, LLC ("Noridian") and CSG Administrators, LLC ("CSG") are two MACs that process claims for DME Suppliers.[2] In addition to processing claims, MACs also issue local coverage determinations ("LCDs") that limit coverage for a particular item or service within their specific region(s). (Exs. B, C).

5. Pursuant to section 731 of MMA 2003, the LCDs were evaluated to determine which ones should be adopted on a national basis for greater consistency. LCDs for Ostomy Supplies (L33828) were published on Noridian's website, which lists all of the MACs, their respective jurisdiction states and territories, and the Coverage Guidance. (Ex. D). Pursuant to criteria inherent in the Social Security Act § 1862(a)(1)(A) provisions, the purpose of an LCD is to provide information on what is "reasonable and necessary." The "reasonable and necessary" criteria are defined by coverage indications, limitations and/or medical necessity.

6. A focal area for the MACs and the aforementioned criteria related to refills of

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[1] Centers for Medicare and Medicaid, *What Is a MAC?*, https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC.html (last visited Jan. 26, 2019).

[2] Centers for Medicare and Medicaid, *DME Jurisdiction Map as of October 2017*, https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/DME-MAC-Jurisdiction-Map-Oct-2017.pdf.

DMEPOS items and supplies. Specifically, as set forth in Exhibit D:

> REFILL REQUIREMENTS
>
> For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized.
>
> For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.
>
> Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the ordering physicians that any changed or atypical utilization is warranted.
>
> Regardless of utilization, a supplier must not dispense more than a one (1) -month supply at a time for a beneficiary in a nursing facility and a three (3) -month supply for a beneficiary at home.

7. CSG's Comprehensive Error Rate Testing ("CERT") program's Annual Medicare Fee-for-Service ("FFS") Improper Payment Rate Report Durable Medical Equipment ("DME") for the 2014 reporting period identified that "approximately 5.1 billion dollars was improperly paid for DMEPOS items. This represents a 53.1 percent improper payment rate for DMEPOS and represents 10.4 percent of the overall improper payment rate." Furthermore, insufficient documentation accounted for ninety-two (92) percent of overall improper payments. 80 Fed. Reg. 81674, 81676 (Dec. 30, 2015).

8. Defendants devised an illegal scheme to knowingly present, and cause to be presented, false or fraudulent claims for various categories of DMEPOS (i.e., ostomy, urologic, diabetic and wound care) to the Federal Programs and private payors. As part of the scheme, Defendants filled and shipped orders without the required pre-authorization and documentation. The scheme resulted in millions of dollars for the Defendants from at least 2011 forward.

9. In order to be eligible for coverage, the Local Coverage Determination ("LCD") (as defined in Section 1869(f)(2)(B) of the Social Security Act) criteria, which is based on Social Security Act §1862(a)(1)(A), must be met. Specifically, the DMEPOS must be "reasonable and necessary" and meet coverage indications, limitations and/or medical necessity.[3]

10. As set forth below, as part of this scheme, from at least 2011 to April 2015, Defendants knowingly submitted claims to Federal Programs for reimbursement for a variety of different types of DMEPOS that were false or fraudulent because they were tainted by non-existent authorizations and inadequate documentation, making the products unreasonable and not necessary, and did not arise from a valid prescriber-patient relationship.

11. During the Relator's tenure between January 2013 and April 2015, Defendant CCS Medical, Inc.'s ("CCS") revenues were derived from Medicare (50%), Medicaid (25%), and commercial payors (25%). The data also showed that the average monthly revenue for the ostomy and urology product lines was approximately $2.5 million, with osmotic constituting approximately $600,000 and urology accounting for approximately $1.9 million.

12. CCS is a supplier of DMEPOS throughout the United States. The primary types of supplies that are at issue in this case are osmotic and urology, wound care and diabetes care.[1]

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[3] Noridian Medicare Audit Contractor, *Local Coverage Determination (LCD): Ostomy Supplies (L33828)*, https://med.noridianmedicare.com/documents/2230703/7218263/Ostomy+Supplies+LCD+and+PA (last visited Jan. 23, 2019).

According to the company website, CCS was "[f]ounded in 1994 as a small enterprise [and] … has grown to become one of the country's leading providers of home delivery medical supplies."[2] The majority of CCS customers are Medicare beneficiaries, and the majority of CCS income is derived from claims that it submits to the Medicare system. In 2011, CCS announced it was relocating from Florida to Texas. It also announced that "CCS Medical is a privately held company and its largest shareholders are funds managed by Highland Capital Management, L.P. [("HCM")]."[3]

13. In addition to having a significant financial interest, HCM co-managed CCS, held at least one seat on the CCS board of directors and conspired with it, and approved and bankrolled its specific plan to keep shipping ostomy, urologic, wound care, diabetic and other DMEPOS items to beneficiaries of Federal Programs, who did not have the requisite authorization, who did not meet medical necessity, and did not want to remove patients from the "Just Ship It" list – even those who were deceased.

14. On April 11, 2013, CCS Medical released a press statement indicating that it was "named a winner in the national Competitive Bidding Program of the Centers for Medicare & Medicaid Services (CMS)." (Ex. E).

> CCS Medical is one of only 18 suppliers awarded CMS contracts to provide mail order diabetic testing supplies at competitively bid prices nationwide and in the four U.S. territories (American Samoa, Guam, Puerto Rico, and the U.S. Virgin Islands). As announced previously by CCS Medical, one of the brands that CCS Medical will be carrying is LifeScan's OneTouch® Ultra® test strips, the No. 1 brand recommended by endocrinologists and diabetes educators.
>
> In addition, CCS Medical was awarded a CMS contract to provide Negative Pressure Wound Therapy (NPWT) pumps to beneficiaries in 87 of the 91 communities across the country that were competitively bid. The Competitive Bidding Program and the National Mail Order Program are scheduled to go into effect July 1, 2013. *Id.*

At the bottom of the press release, CCS boasts that "it is a privately held company and its

largest shareholders are funds managed by Highland Capital Management, L.P."

15. The intentional falsification of records by Defendants occurred with respect to a significant portion of the claims submitted to Medicare and Medicaid. This knowing falsification by CCS was done with the knowledge of, and encouragement by, CCS executives (e.g., the COO), in addition to at least one of HCM's upper management (e.g., D.B., the HCM Portfolio Manager/Operating Partner on-site at CCS).

16. When the Relator was transferred to the Ostomy and Urological Department, he soon realized that on a national basis, customers were receiving product(s) they should not have received for a number of reasons: (a) the customer was deceased, and the CCS system was never updated; (b) the customer moved and CCS was still sending product to the old address; (c) the medical documentation was inadequate and did not meet CMS regulatory requirements; and (d) CCS was sending the more expensive product (A 4353) rather than the less expensive product (A 4351) because the reimbursement was much higher, despite not having the documentation to meet medical necessity, which resulted in CMS denials of payment.

17. As set forth in more detail below, Defendants knowingly and willfully submitted false or fraudulent claims to the Federal Programs with the sole purpose of increasing the corporate valuation of CCS.

18. Relator brings this suit on behalf of the United States to help it recover monies improperly paid as a result of Defendants' deliberately deceitful conduct.

II. PARTIES

The Relator and Government Plaintiff

19. Relator, Frederick Curcio, IV, MBA ("Relator" or "Mr. Curcio") is a resident of Dallas, Texas. Mr. Curcio worked for CCS from January 2013, as the National Director of Sales

in the Wound Care Department. Between May 2013 and April 2015, he became the National Director of Operations for the Ostomy and Urological Department. Mr. Curcio accepted a position without awareness of the underlying unscrupulous business practices that were pervasive through the Defendants' corporate entities. When he raised questions, he was offered unreasonable explanations by the Defendants. Mr. Curcio did not cultivate any illicit ideas, eschewed promulgating any unprincipled initiatives, and refused to participate in any kickback promotions from vendors. Instead, Mr. Curcio questioned the Defendants' practices, confronted senior management with evidence, and strived to change internal practices within a corrupt corporate culture.

20. While employed full-time at CCS, through his participation in meetings, e-mails, memoranda, and the like, Relator acquired extensive, first-hand, and inside knowledge of the schemes that form the basis of this Complaint. The Federal Programs, private payors and patients/customers were located nationwide. Specifically, CCS engaged in interstate commerce by shipping different durable medical goods (e.g., ostomy, urologic, diabetic and wound care), to customers located in every Medicare Region.

21. Notably, in his role as a senior manager, Mr. Curcio acquired substantial knowledge of CCS practices and claims submissions to the Federal Programs and private payors through his direct observations, independent, personal knowledge of Defendants' conduct, and documents in his possession. He also regularly interacted with the CCS executive team, including individuals from HCM, and was privy to the Defendants' business operations – including the fraud at issue. Mr. Curcio is the original source of the information underlying this Complaint and has provided substantially all material evidence and information in his possession to date, as required by the False Claims Act. Mr. Curcio was not the "mastermind" of the fraud, nor was he providing

directives; rather, the longer he stayed at CCS, the more he learned about the fraud, as well as the individual Defendants' roles. The United States is an appropriate party plaintiff for the Claim of Relief by virtue of the False Claims Act, 31 U.S.C. § 3730(b). Mr. Curcio brings this Claim for Relief in the name of the United States of America.

22. The United States is a Plaintiff for which recovery is sought for damages on behalf of the Department of Health and Human Services ("HHS"), the Department of Defense ("DOD"), the United States Department of Veterans Affairs ("VA"), the Center for Medicaid and Medicare Services ("CMS"), the Federal Office of Personnel Management and other relevant federal programs.

Defendants – CCS Medical and DEGC

23. Defendant, CCS Medical, Inc. ("CCS") is a Delaware corporation with its principal office located at 1505 LBJ Freeway, Suite 550, Farmers Branch, Texas 75234. CCS transacts business in the State of New Jersey, as well as other locations throughout the United States.[6]

24. Defendant, DEGC (U.S.) Inc. ("DEGC"), a related entity of CCS, is a Florida corporation with its principal office located at 1505 LBJ Freeway, Suite 550, Farmers Branch, Texas 75234. DEGC transacts business in the State of New Jersey, as well as other locations throughout the United States.

Highland Capital Management, LP

25. Defendant Highland Capital Management, LP ("HCM") is a Delaware corporation with its principal office located at 300 Crescent Court, Suite 700, Dallas, Texas 75201. HCM transacts business in the State of New Jersey, as well as other locations throughout the United States and exercised control over CCS.

26. HCM "is a multibillion-dollar global alternative investment manager,"[4] which has a

substantial investments in CCS.[5]

27. HCM acquired its interest in CCS in 2011 and maintained a significant level of involvement in the business and operations of CCS. For example, D.B., HCM Portfolio Manager/Operating Partner, was affiliated with HCM from October 2007 through October 2015. Simultaneously, D.B. also served as a member of the Board of Directors at CCS Medical. D.B. was also on-site and hands-on at CCS. In 2013, HCM assumed active control over CCS and appointed a new management and operations team, who were tasked with guiding the strategic direction of CCS.

28. Relator has named the private equity group HCM as a defendant, because according to its Form N-CSR for the fiscal year ending December 30, 2012, the Highland Floating Rate Opportunities Fund had CCS Medical, Inc. (Senior Loans) and CCS Medical, Inc. (Common Stock) as two of its Top 10 Holdings as of 12/31/12. The Principal Amount ($) of US Senior Loans showed CCS Medical, Inc. with a First Lien Term Loan of 8.25%, 03/31/15 (b) with a value of $29,672,902. Comparatively, HCA, Inc. had a Tranche B-3 Term Loan of 3.46%, 05/01/18 with a value of $5,677,184.[4]

29. Additionally, HCM's "Floating Rate Opportunities Fund held at least five percent of the outstanding voting securities of the following companies as of December 31, 2012" – CCS Medical, Inc. (Senior Loans) and CCS Medical, Inc. (Common Stocks).[5]

30. Collectively, CCS (including its sister companies and subsidiaries), DEGC and HCM are known as the "Defendants."

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[4] U.S. Securities and Exchange Commission, *Form N-CSR Highland Capital Management – Highland Funds I*, p. 10 (Dec. 31, 2012), https://www.sec.gov/Archives/edgar/data/1354917/000119312513098634/d453209dncsrs.htm.

[5] *Id.* at 48.

III. JURISDICTION, VENUE, AND DISCLOSURE STATEMENT

31. This Court has subject matter jurisdiction over these claims brought under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, pursuant to 31 U.S.C. §§ 3730 and 3732. This Court has supplemental jurisdiction to entertain potential common law causes of action, such as unjust enrichment under 28 U.S.C. §§ 1345 and 1367(a).

32. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because that section of the False Claims Act authorizes nationwide service of process, and because the Defendants engage in interstate commerce with the both the Department of Health and Human Services and the New Jersey Department of Human Services, Division of Medical Assistance and Health Services, and transact business in this State. All Defendants have at least minimum contacts with the United States, and can be found in, reside, or transact or have transacted business, in the State of New Jersey. Specifically, the State of New Jersey is where the various DMEPOS were shipped to and where statements and claims for payment initiated and where the fraud was perpetrated on the State of New Jersey's Medicaid Program and Medicare beneficiaries commencing before Relator's start date in January 2013, and continuing throughout his employment, despite his efforts to comply with the relevant laws and regulations.

33. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and under 28 U.S.C. §§ 1391(b) and 1395(a), because the Defendants transact business in the State of New Jersey and with the New Jersey Department of Human Services, Division of Medical Assistance and Health Services, P.O. Box 712, Trenton, New Jersey 08625-0712.

34. There have been no public disclosures of the allegations and transactions contained herein that bar jurisdiction under 31 U.S.C. § 3730.

35. Relator is unaware of any public disclosures. To the extent there has been such a

public disclosure of any of Relator's allegations herein, he is an original source of those allegations within the meaning of 31 U.S.C. § 3730(e)(4)(B). Relator possesses direct and independent knowledge of the information on which the allegations are based. Relator also voluntarily disclosed to the Government this information prior to any public disclosure. *See* 31 U.S.C. § 3730(e)(4)(B).

IV. STATUTORY BACKGROUND

The False Claims Act

36. Originally enacted in 1863 during the Civil War, the False Claims Act was substantially amended by the False Claims Amendments Act of 1986, signed into law on October 17, 1986; and by the Fraud Enforcement and Recovery Act of 2009, which was signed into law on May 20, 2009. Congress's intent was to enhance the Government's ability to recover losses sustained as a result of fraud against the United States and to provide a private cause of action for the protection of employees and others who act in furtherance of the purposes of the Act. Congress acted after finding that fraud in federal programs and procurement is pervasive and that the Act, which Congress characterized as the primary tool for combating fraud in government contracting, needed to be modernized.

37. The False Claims Act establishes civil penalties and treble damages liability to the United States for violations of the Act including, among other things: knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval; and knowingly making, using, or causing to be made or used, a false record or statement material to a false claim. 31 U.S.C. § 3792(a)(1).

38. To show that an entity acted "knowingly" under the False Claims Act, it must be proven that the entity, with respect to information: (1) has actual knowledge of the information;

(2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. It is not necessary to prove that the entity had the specific intent to defraud the United States. 31 U.S.C. § 3729(b)(l).

39. Under the False Claims Act, the United States is entitled to recover three times the amount of each claim and, for each claim or overpayment, a civil penalty of not less than $5,500 and not more than $11,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 for violations that occurred prior to November 2, 2015 and not less than $11,181 and not more than $22,363 for violations that occurred after November 2, 2015.

40. As the FCA's legislative history illustrates, "[c]laims may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program."[6] There are three broad categories of claims: (1) reverse false claims; (2) factually false; and (3) legally false claim.

41. A reverse false claim occurs when any person knowingly and improperly avoids or decreases an "obligation" to pay the government in violation of 31 U.S.C. § 3729(a)(1)(G).

42. A factually false claim is defined as an "incorrect description of goods or services provided or a request for reimbursement for goods or services never provided."

43. Legally false claims are predicated on an express or implied false certification of compliance with a regulation, statute or contract term. *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S.Ct. 1989, 1999 (2016) established that both express and implied legally false claims may form a valid basis for a False Claims Act case. When evaluating a legally false claim, the United States Supreme Court, in *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S.Ct. 1989 (2016) required that a plaintiff/relator substantiate that compliance with the

[6] S. REP. No. 345, 99th Cong., 2d Sess. 9 (1986), *reprinted in* 1986, U.S.C.A.A.N. 5266, 5274.

regulations was material to the government's decision to pay, and that the defendants had knowledge of the falsity of the claim.

44. Compliance with a variety of laws and regulations is material to the government's decision to pay claims for DMEPOS. "In general, a false statement is material if it has 'a natural tendency to influence, or [is] capable of influencing, the decision of the decision-making body to which it was addressed.'" *Neder v. United States*, 527 U.S. 1, 16 (1999) (quoting *United States v. Gaudin*, 515 U.S. 506, 509 (1995); cited by *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S.Ct. 1989, 1999 (2016)).

The Anti-Kickback Statute

45. The Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7(b)(2), was enacted by Congress to prevent improper financial considerations from influencing the amount, type, costs or selection of health care services financed to any extent by the U.S. Treasury.

46. Kickbacks come in different forms, whether directly or indirectly, in cash or in kind, which include, but are not limited to cash, gifts, supplies, long-term credit arrangements, equipment, and services.

47. It is remuneration, or merely the offering of it, to induce payments by federal programs, that transforms an ordinary, lawful transaction into one that violates the AKS.

48. The AKS broadly defines an "inducement" (i.e., a kickback) to mean "any money, fee, commission, credit, gift gratuity, thing of value, or compensation of any kind which is provided, directly or indirectly, to any prime contractor, prime contractor employee, subcontractor or subcontractor employee, for the purpose of improperly obtaining or rewarding favorable treatment in connection with a prime contract or in connection with a subcontract relating to a prime contract." 41 U.S.C. §§ 52-53.

49. The AKS provides both civil and criminal penalties for offering or paying remuneration to induce someone to refer patients to or for, or to purchase, lease, or order, any item, service or facility for which payment may be made by a federally funded health care program. 42 U.S.C. § 1320a-7(b). This prohibition applies whether the financial benefit is provided directly or indirectly, "in cash or in kind."

50. Compliance with AKS is a prerequisite for receiving payment from federal health care programs.

51. In 2010, Congress amended the AKS when it enacted the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 11-148, 124 Stat. 119 (2010). The amendment makes clear that claims that are influenced in any way by kickbacks are, by definition, false claims under the FCA. PPACA, 124 Stat. 119 § 6402(g) (amending Section 1128B of the Social Security Act, 42 U.S.C. § 1320a-7(b)(g).

52. PPACA Section 6402(f)(1) amended the AKS to clarify that specific intent to violate the AKS or actual knowledge of the kickback is not required under the FCA. This was codified at 42 U.S.C. § 1320a-7(b)(h).

53. When a DMEPOS supplier utilizes kickbacks (e.g., waiving insurance co-pays and shipping more products than was medically necessary for free) and illicit telemarketing, the kickback taints the entire claim and all related services, regardless of any medical basis for its use. The kickback inherently creates a conflict of interest, potentially putting the patient at risk.

54. A kickback is material if it has a natural tendency to influence or is capable of influencing a decision maker to which it is addressed. With DMEPOS either the physician and/or the patient may be considered the decision maker. All of the Defendants' kickbacks are material.

55. The Government is not required to pay for products or services tainted by kickbacks

because, under such circumstances, the Government has no assurance that the product or services were provided in the best interests of the patient.

V. AFFECTED HEALTHCARE PROGRAMS

Medicare

56. The Medicare Program ("Medicare") is a federal health insurance program established by the Social Security Act of 1965 to assist qualified aged and disabled individuals, referred to as "Medicare beneficiaries." Medicare is administered by the Centers for Medicare & Medicaid Services ("CMS"), a federal agency under the United States Department of Health and Human Services. Medicare reimburses health care providers and suppliers for the costs of health care services and items provided to Medicare beneficiaries.

57. Payments from the Medicare Program come from a trust fund (the Medicare Trust Fund) which is funded through payroll deductions taken from the work force, in addition to government contributions. For close to fifty years, the Medicare Program has enabled the elderly and disabled to obtain necessary medical services from medical providers throughout the United States.

58. Much of the daily administration and operation of the Medicare Program is managed through private insurers under contract with the federal government.

59. Medicare now has four parts: Part A; Part B; Part C; and the Part D Program. Medicare Parts B, as well as Medicaid and other government programs, are at issue in this case.

60. Medicare Part A (Hospital Insurance) helps cover inpatient care in hospitals, including critical access hospitals, and skilled nursing facilities (not custodial or long-term care). Medicare Part A also helps cover hospice care and some home health care.

61. Medicare Part B (Medical Insurance) helps cover doctors' services and outpatient care, as well as other medical services not covered by Part A. Part B also helps pay for covered health

services and supplies when they are medically necessary. Under Medicare Part B, the federal government contracts with insurance companies and other organizations known as "carriers" to handle payment for physicians' services in specific geographic areas. These private insurance companies, or "Medicare Carriers," are charged with and responsible for accepting Medicare claims, determining coverage, and making payments from the Medicare Trust Fund.

62. To become a Medicare Part B supplier of durable medical equipment, prosthetics, orthotics, and supplies (a "DMEPOS supplier"), as well as maintain such status, Defendants CCS and DEGC were required to complete and submit an enrollment application with the government, via its National Supplier Clearinghouse ("NSC").

63. Enrollment as a Medicare DMEPOS supplier is mandatory in order to be eligible to receive Medicare payments. To be accepted and enrolled as a Medicare DMEPOS supplier, entities are required to meet "supplier standards," which are codified at 42 C.F.R. § 424.57 and explicitly included in the enrollment application itself.

64. Pursuant to that regulation, an applicant must certify – under oath – that it complies with those supplier standards. Only upon doing so (and otherwise meeting the application criteria) can a prospective DMEPOS supplier be enrolled and receive a National Provider Number ("NPI") necessary for billing purposes. *See* 42 C.F.R. § 424.57(c)(1) - (26). Defendant CCS (and its related companies) applied for and received NPIs.

65. According to the regulations, an applicant must "meet and must certify in its application for billing privileges that it meets and will continue to meet" all of the supplier standards. 42 C.F.R. § 424.57(c).

66. Suppliers, via their authorized and/or delegated officials, must also certify that they "will not knowingly present or cause to be presented a false or fraudulent claim for payment by

Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity." A supplier must make this certification both to initially obtain a NPI and Medicare billing privileges, and also on every occasion that the supplier re-enrolls or updates its enrollment. DMEPOS suppliers are required to re-enroll and re-certify compliance with the supplier standards at least every three years. *See* 42 C.F.R. § 424.57(g).

67. A Certificate of Medical Necessity ("CMN") or a DME Information Form ("DIF") is a form required to help document the medical necessity and other coverage criteria for selected durable medical equipment, prosthetics, orthotics, and supplies items. CMNs contain sections A through D. Sections A and C are completed by the supplier and Sections B and D are completed by the physician. A DIF is completed and signed by the supplier. It does not require the cost, a narrative description of equipment or a physician's signature.

68. For certain items or services billed to a DME MAC, the supplier must receive a signed CMN from the treating physician or a signed DIF from the supplier. A supplier must have a signed order and an electronic CMN or DIF in their records before they can submit a claim for payment to Medicare. CMNs or DIFs have a DME MAC form number (e.g. 01, 02, 03) and a revision number (e.g. .01, .02). Some forms also have an alpha suffix (e.g. A, B, C).

69. The Healthcare Common Procedure Coding System ("HCPCS") includes "[s]tandardized code sets [which] are necessary for Medicare and other health insurance providers to provide healthcare claims that are managed consistently and in an orderly manner."[7] DMEPOS supplies, which were supplied by Defendants and their related persons, are coded at HCPCS Level II. Adequate documentation, such as a physician authorization, is required in order to establish

[7] APPC, *What is HCPCS?*, https://www.aapc.com/resources/medical-coding/hcpcs.aspx (last visited Jan. 14, 2019).

medical necessity[8] for numerous DMEPOS supplies. *The Medicare Claims Processing Manual, Chapter 20 – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies* (DMEPOS) (Rev. 4001, Mar. 16, 2018) (the "*Manual*"). As referenced in the *Manual*, 42 C.F.R. § 400.202 provides general instructions on billing and claims processing: "[a] DMEPOS supplier must meet certain requirements, and enroll as described in Chapter 10 of the Program Integrity Manual." By attesting to satisfying certain requirements, a DMEPOS supplier is affirming that it is compliant.

70. The enactment of the Affordable Care Act, Pub. L. 111-148 (Mar. 23, 2010) ("ACA") established a new section of the Social Security Act. Specifically, ACA Section 6402(a) created Section 1128J(d)(1) of the Social Security Act (the "Act"). Section 1128J(d)(2) of the Act requires that once an overpayment is identified, that it is reported and returned within 60 days or the date that any corresponding cost report is due.

71. On February 12, 2016, the U.S. Department of Health and Human Services published its Final Rule relating to the obligations of suppliers and providers receiving remuneration through the Medicare program to "report and return overpayments by the later of the date that is 60 days after the date on which the overpayment was identified." 81 Fed. Reg. 7654 (Feb. 12, 2016). Reporting and returning an overpayment as defined in the False Claims Act, 31 U.S.C. § 3729(b)(3) is explicitly stated in "section 1128J(d) of the Act, which states that any overpayment under this rule is an obligation for purposes of the FCA." 81 Fed. Reg. 7654, 7665 (Feb. 12, 2016). In turn, this triggers liability as a reverse false claim under 31 U.S.C. § 3729(a)(1)(G) for failing to report and return overpayments from Medicare Parts A&B.

[8] 42 C.F.R. § 88.14, https://www.gpo.gov/fdsys/pkg/CFR-2012-title42-vol1/pdf/CFR-2012-title42-vol1-sec88-14.pdf (last visited Jan. 14, 2019).

72. Defendants, acting by and through certain of their officers and employees in concert with each other, did knowingly conspire, confederate, and agree to violate various laws and regulations governing claims submission to the various federal and state government agencies, and to retain the overpayments by these Federal Programs.

73. Relator was employed in various positions with CCS from January 2013 into April 2015, including Director of Operations/Sales. Mr. Curcio's position required him to evaluate revenues, practices, policies and data on a national basis from both a historic and present perspective.

74. Since at least 2011, CCS has enrolled patients in, and billed the Federal Programs for, DMEPOS products (e.g., ostomy, urologic, wound care and diabetic), despite knowing that these patients were not eligible for Federal Program coverage of these DMEPOS because they did not meet the requisite eligibility requirements and/or no doctor's order had been obtained.

Medicaid

75. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a State Medicaid program.

76. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A).

77. Medicaid does cover DME, as long as the supplier has obtained the documentation necessary to support the medical necessity and the authorization requirements.

Additional Government Programs and Private Payers

78. The Federal Programs and private payors were located nationwide. The scope of the

broad systemic scheme by CCS to defraud all federal programs, not just Medicare and Medicaid, includes but is not limited to the following:

Table 1

Insurance Plan (ID)
AETNA HMO/EPO (71840)
AETNA PPO, POS & INDEMNITY (69029)
AETNA US HEALTHCARE (75422)
AMERIHEALTH ADMINISTRATORS (67228)
ANTHEM BCBS OF CONNECTICUT (69378)
ANTHEM BCBS OF MAINE (68371)
ANTHEM BCBS OF MAINE FEDERAL (64508)
BCBS OF DELAWARE FEDERAL (714)
BCBS OF TEXAS FEDERAL (69155)
BLUE CROSS OF IDAHO HMO/PPO (66272)
BLUE SHIELD/ANTHEM BC OF CA FEDERAL (70875)
CHAMP VA (65320)
MEDICARE REGION A (66038)
MEDICARE REGION B (66039)
MEDICARE REGION B SECONDARY (70548)
MEDICARE REGION C (64968)
MEDICARE REGION C SECONDARY (69900)
MEDICARE REGION D (66040)
REGION D MEDICARE/MEDI-CAL 2NDRY (75122)
TRICARE NORTH (66539)

TRICARE SOUTH (67655)

79. Defendants have submitted and caused to be submitted thousands of false and fraudulent claims to federal and state-funded health care programs for DMEPOS products. Each submission is a false or fraudulent claim in violation of the federal False Claims Act.

80. CCS utilized the Patient Information Management System ("PIMS"), which was governed by the *IOU Department PIMS Manual (v.2)*.[9] The PIMS System was supposed to be utilized for patient information monitoring, tracking utilization information, and revenue cycle management. "It holds all of the patient's demographic, treatment, and account information." A CCS employee could drill down further and view the following items: (1) demographic snapshot; (2) standard shipment snapshot; (3) documentation snapchat; (4) treatment snapshot; and (5) notes snapshot.

81. A particular item to note is the *Standard Shipment Snapshot* on page 8 of the *PIMS Manual*. This feature "allows the user to see basic information about the patient's shipment types and history." A CCS employee could drill down further and see fundamental information about types of documents (i.e., PWO, Test Log) and the frequency of use, thereby providing a comprehensive analysis with the "click of a mouse," which the Defendants chose to ignore in order to increase revenues by continually submitting false claims to both Federal Programs and private payors.

VI. THE FRAUDULENT SCHEMES

82. CCS submitted false or fraudulent claims for diabetic, urologic, ostomy and wound

[9] The PIMS System was comprehensive and sophisticated; yet, easy to navigate. Defendants chose not to use the snapshot filters, which would have given them a detailed roadmap for each patient. Tellingly, the sole metric on which the Defendants focused was the purported total number of patients, rather than a true and accurate tally of patient.

care products to federal and state programs for payment, knowing that the claims had material defects, for which the government would deny payment. Specifically, having an inadequate compliance program, waiving copays in violation of the AKS, failing to obtain the appropriate PWO, patient authorization and/or medical necessity (e.g., no charts or urinalysis with inadequate number culture units), shipping to deceased individuals, over shipping products that were not paid for and were not returned, and utilizing telemarketing (i.e., autodialing without written patient consent) – was a practice that began in the diabetes division and was later applied to wound care, urology and ostomy, at the direction of CCS's Chief Executive Officer, who was put in place by HCM.

Inadequate Compliance Program and Inadequate Statistical Sampling

83. Organizations that file claims for reimbursement by Medicare are required to "[a]dopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS's program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse." 42 C.F.R. § 422.503(b)(4)(iv). Compliance programs are required to include certain minimum requirements, which include but are not limited to written policies and procedures, corporate statements indicating the entity's commitment to a culture of compliance with all applicable federal and state laws and standards, designating a compliance officer and implementing adequate training programs.

84. To the extent required by law, the Defendants did not meet the requirements for an adequate compliance program despite having a *CCS University IOU Manual*. If a viable compliance program existed, then the underlying fraud would not have been present because it would have been addressed. Instead, fraudulent claims were submitted to the United States Government for payment, even though the Defendants knew that co-pays were illegally being

waived, medical necessity and appropriate authorization forms were not present, and telemarketing was used to induce Medicare beneficiaries to utilize CCS Medical and its related companies' products without a prior, written authorization and payments from the Government were knowingly retained by Defendants. Instead of taking the ethical and legal path of self-reporting and returning money to the Government, the Defendants knowingly retained the payments in order to increase revenues and skew the valuation of CCS.

85. An item related to an adequate compliance program and identifying the number of overpayments is "reasonable diligence" over a 6-year lookback period. 81 Fed. Reg. 7654 (Feb. 12, 2016). "Reasonable diligence includes both proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments and [reactive] investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment." *Id.* at 7661. Defendants conducted internal audits; however, the audits did not meet the Office of Inspector General's Self-Disclosure Protocol of 30 samples for a Probe Sample. *See* CMS Medicare Program Integrity Manual, Chapters 3.10.1.3, 3.11.12. Two of CCS's internal audits demonstrate the material deficiencies in its compliance efforts.

86. The May 22, 2013 Internal Memo between the VP – Urology Operations to the VP – Compliance Officer addressing the *IOU Internal Audit Results – Q1 2013* indicates the following, as shown in Table 2:

Table 2

Item	**Outcome**
What we reviewed:	· Randomly reviewed 29 Medicare claims for ostomy and urology supplies (Incontinence products are non-covered by Medicare).

	· Reviewed the claims against Medicare National and Local Coverage Determinations. · Review did not include physician medical records. · Dates of Service between November 2012 and January 2013.
Summary of Results:	Anticipated Denial Rate: **58%**
Identified Errors:	**58%** (17 out of 29) – Missing Refill Consent (ex: PID 85019, PID 89938, PID 371929, PID 456486).[7] Medicare guidelines require DME providers to document quantity on hand remaining for consumable supplies including Ostomy and Urology products when obtaining consent for refill of orders.[8] Based on Compliance's review of the claims, it appears CCS Medical's ostomy and urology intake team is asking and documenting supply on hand when the consent is obtained verbally; however, the paper and electronic reorder cards fail to document quantity of supply remaining.

87. The questionable January 26, 2014 Internal Memo from the Compliance Analyst II, CHC, the *Urological and Ostomy Internal Audit Results – Q3 2014*, indicates that there were problematic claims from dates of service ranging from August 26, 2014 to September 26, 2014. Some of the issues are as follows:

Table 3

Item	Outcome
Identified Errors:	Number of errors may exceed the internal error rate due to multiple errors found per claim.
Overall PWO Errors:	1. PWO not amended per Medicare requirements (i.e., Physician name was hand written without initial and dating the changes on the PWO); error found on 4/25 claims; PIDs 1892662, 1461355, 1362960, 1362960. Re-educate staff on Medicare PWO/medical record amendment requirements. Incorrect information must be crossed out and added information must be initialed and dated by the author of the amendment; this requirement applies when author is just adding name/NPI to the PWO. 2. PWO did not authorize or equal calculated quantities shipped and billed; error found on 2/25 claims; PIDs 1375767, 1353609; Action Needed: Re-educate staff on Medicare requirements for filling written orders. 3. Supplies ordered on PWO had frequency or quantity that was not legible; error found on 1/25 claims; PID 2251884; Action Needed: Re-educate staff on the importance of collecting/accepting legible documentation.
Billing Errors:	4. Signing treating physician from PWO does not match treating physician billed; error found on 3/25 claims; PIDs 1892662, 1461355, 1362960; Action Needed: Perform training reminder to verify billed physician matches current PWO physician and make any necessary system updates for future claims.
Overutilization Errors:	5. Quantity billed exceeded time

	limitations indicated by LCD for A5120 (we billed 150 quantity every 3 months vs LCD allowable of every 6 months); error on 1/25 claims; PID 1892662; Action Needed: Re-educate staff on Medicare coverage limitations requirements. 6. Exceeding LCD quantity limits for certain items sent; (A 4432 is limited to 20/month and we sent 120); error found on 1/25 claims; PID 1892662; Action Needed: Re-educate staff on Medicare refill too soon rules.
Refund Errors:	7. Returned supplies received but refund to Medicare not completed within 60 days; error found on 1/25 claims; PID 1304670; Action Needed: Re-educate staff on timely completion of refunds when an item is received through Returns.

88. Defendants had the knowledge that false claims were being submitted to the government; yet, they chose to ignore their own internal recommended corrective action items.

Fraudulent Bills for Monthly Supplies.

89. A CCS Excel spreadsheet entitled *Deactivations by Reason 1.1.14-2.28.15* indicates a significant number of patient names, insurance identifiers, CCS products, and the reason(s) that patients should not have been counted as current. This is significant because more product was being shipped or auto shipped than was permissible under the Medicare regulations, patients did not have current POWs on file, and deceased clients' claims continued to be shipped and payments from government and private payors were knowingly retained in violation of the 60-day Rule. Examples as to why these patients were not current include the following: deceased patients; change of insurance; or updated condition or diagnosis. Tab 2 lists the specific patients. TB, the CCS Director of Operations, relayed to Mr. Curcio that the Defendants wanted to leave

persons on the books in order to skew the valuation of CCS to increase its value in a HCM Fund, with the knowledge that false claims for payment were being submitted to both government and private payors. By skewing the number of patients and the average revenue per patient, CCS knowingly collaborated with HCM to increase the valuation of tis funds holding shares in CCS through Potemkin Village valuations. The reasons for this practice were two-fold in relation to the corporate valuation: (1) the number of patients; and (2) overall revenue and average revenue per patient.

90. CCS fraudulent billing has taken several forms. Since at least 2011, CCS has automatically billed the Federal Programs for a variety of DMEPOS products provided to patients despite CCS's failure to assess and document these patients' continued need for, and use of, these products. As a result, for years, CCS has billed government-funded health care programs for DMEPOS products provided to patients who were ineligible for the DMEPOS and/or no longer using them.

91. As noted previously, in some instances, not only were the DMEPOS products not medically necessary, they were shipped to deceased individuals.

False Claims Resulting from Failure to Obtain Authorizations and/or Recertifications.

92. Despite the push from management to increase sales and to continue the "Just Ship It" practice, Mr. Curcio tasked his team to implement compliance-minded procedures. For example, some of the Healthcare Common Procedure Coding System ("HCPCS")[9] codes for actual items with a A4353 HCPCS code were wrongfully listed in the CCS internal system, indicating that Federal Programs and private payors were being billed for false claims that were submitted. Relator attempted to rectify the situation by updating the internal system to reflect the correct HCPCS code.

93. During the regular course of business, Autoship Analyses were performed between June 2013 and December 2014. These various excel sheets show that certain patients were missing physician work orders ("PWOs"), show that items were automatically shipped to payments who were deceased, had moved, had inadequate prescriptions and PWOs, and that Defendants never received payments, yet CCS booked revenue at the time of shipment.

94. Certain Autoship Analyses also identified the category of product, as well as the insurance entity, which was broken down to the region and state level. The list below in Table 4, compiled at the direction of Relator, is a sample of patients with missing authorizations:

Table 4

Patient ID	**Shipment Type (30 or 80)** **(30 = Ostomy)** **(80 = Urologic)**	**Insurance ID**	**Insurance Name**
2990900	80	46714	Great West Insurance
1352199	80	61758	Medicaid of Maryland
1354963	80	63650	Blue Shield of California
1333450	80	67728	Medicaid of California
2758950	30	69181	Mail Handlers Benefit Plan
1338764	80	70765	Medicaid of TX – over 21/TITLE XIX
2648581	80	76624	NY State Insurance Workers Comp.
1913847	30	129	CHAMP VA

95. The above examples demonstrate that the Defendants were not only aware that employees were falsifying customer records, at least from 2011 to 2015, but that the Compliance Department would even coach employees in writing, while turning a blind-eye in practice. The

"chiseling" of internal documentation was not a hidden or a secretive activity because the data was readily available in *PIMS System* and other software systems. These activities stem back at least 10 years, under the leadership of TB, who, as CCS Director of Operations, was overseeing both revenue cycle management and operations. TB directly contributed to the issues that Relator raises in this Complaint and attempted to raise during his tenure at CCS. TB focused on phone metrics and intentionally did not address the compliance issues or blatant false claims metrics that were contained in the *PIMS System*. Rather, the activity was well established, well known, and well understood within CCS and HMC. The activities were not hidden, rather, they were condoned and encouraged.

96. In May 2013, shortly after Relator took over as Director of Operations/Sales of the Ostomy and Urological Division, he had a conversation with TB, during which he asked her why there were a significant number of inactive patients in company records. TB replied to Relator "she was told not to delete them by upper management, in order to inflate the patient base."

97. Despite TB's order, Mr. Curcio attempted to find the actual number of active patients. An Excel sheet analysis entitled *CCS Medical, Inc. Active Patients Trend* was conducted and showed changes between January 2014 and January 2015 in all areas except for wound care. The purpose was to identify which of the patients were in fact "inactive" versus active. Over the year long process, a variance of 53,777 patients was identified.

Table 5

Active Patients by Product Line	**January 2014**	**January 23, 2015**
Non-Insulin	183,225	138,467
Insulin	47,085	48,472
Pharmacy	10,307	6,678

Urological	6,523	5,198
Ostomy	5,640	4,343
Incontinence	4,172	17
Product line total	256,952	203,175

98. These examples establish that Defendants knew that their conduct was nefarious and illegitimate – both in the submission of false claims and the retention of payments made by the government from at least 2011 through April 2015. Upon information and belief, the Defendants conduct continues to this day.

False Claims Resulting from Waiving Co-Pays in Violation of the Anti-Kickback Statute

99. "Medicare pays for durable medical equipment, prosthetics and orthotics … on the basis of 80 percent of the lesser of – (1) The actual charge for the item; (2) The fee schedule amount for the item[.]" 42 C.F.R. § 414.210(a). Beneficiaries are responsible for a 20% copay or coinsurance.

100. Defendants knew that this requirement existed and even created an Excel spreadsheet, *319 Uro OstCopayCalculator_10July2013.xls*, which detailed the HCPCS code, the amount allowable by Medicare, a product description and the 20% copay to be paid by the patient.

				% TO BE PAID BY PATIENT	20%		
HCPCS	Mod	Mod 2	Medicare Allowable	Description	Patient Price / Item	Insert # of Billing Units	Line Item Total
A4217			$3.40	Sterile water/saline, 500 ml	$0.68		$ -
A4217	AU		$3.40	Sterile water/saline, 500 ml	$0.68		$ -
A4310			$8.34	Insert tray w/o bag/cath	$1.67		$ -

A4311			$15.89	Catheter w/o bag 2-way latex	$3.18		$ -
A4312			$19.52	Cath w/o bag 2-way silicone	$3.90		$ -

101. Historically, CCS waived or simply didn't collect deductibles and/or copayments. During Mr. Curcio's tenure, a process was implemented to start collecting deductibles and copayments. A specific plan, *OU Patient Pay Strategy FINAL (2)*, was finalized and implemented. In 2015, for the first 45 days of the calendar year, CCS decided to hold claims until the patient deductible balance was $0, so it would not have to try and collect the deductible. This strategy is substantiated by the document, *Deductible draft table rev 120514_15Dec2014*. Different collection processes existed for different payors.

102. Defendants have engaged in a systemic scheme to defraud the United States by fraudulently billing government-funded health care programs for DMEPOS that were billed in violation of the rules of Medicare, Medicaid and other government-funded healthcare programs because CCS knowingly and intentionally waived co-pays in violation of the Anti-Kickback Statute.

False Claims Resulting from the Knowing Retention of Overpayments by Payors

103. Defendants' fraudulent billing has taken several forms. Since at least 2011, CCS has automatically billed Medicare and Medicaid for diabetic, wound care, ostomy, urological incontinence products, despite the following: waiving co-pays without out establishing financial eligibility; shipping products without the appropriate authorizations and/or without adequate medical necessity; over-shipping free supplies; and or utilizing telemarketing without assessing and documenting the patients' continued need for, and use of, these products. Resultantly, for months and sometimes years, CCS has billed and upon information and belief continues to bill

government-funded healthcare programs for services provided to patients who were ineligible for the products and/or no longer utilizing them.

104. In these ways, Defendants submitted and cause to be submitted thousands of false and fraudulent claims to federal and state-funded health care programs for diabetic, wound care, ostomy and urological products. CCS knew that retaining overpayments gained by the submission of false claims was material to the government paying the claim because, as Section 3.6 of the *TRICARE Durable Medical Equipment Payment Appendix*, which became effective on April 1, 2013 indicates, "[i]n the event that UMVS determines that an overpayment to Provider has resulted due to Provider's failure to fully disclose changes to Customary Charges affiliated codes reimbursed at the Default Rate, or due to the Provider providing inaccurate information, or due to Provider providing incorrect estimates of the adjustments needed to the information, or due to Provider providing incorrect estimates of the adjustments needed to the contract rate UMVS may recover those overpayments." (Ex. F).

105. During his employment at CCS, Mr. Curcio raised the issue of returning payments with D.B. and others at both CCS and at HCM during various meetings; however, his suggestion was repeatedly ignored. Each submission was not only false or fraudulent, as the internal audits indicated, CCS knew that there were errors and did not return the payments to either federal or state-funded health care programs.

False Claims Resulting from the Use of Prohibited Autodialing/Telemarketing Activities

106. DMEPOS claims are billed to Medicare through Durable Medical Equipment Regional Carriers ("DMERC") using either Form CMS-1500 or electronic equivalents. As previously stated, the claim forms require the supplier to certify that the information contained on the form "is true, accurate and complete" and to certify that the supplier understands "that any

false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws." Form CMS-1500.

107. Medicare is prohibited from paying "for any item subsequently furnished after unsolicited contacts," 42 U.S.C. § 1395(a)(17)(B), and "suppliers engaging in a pattern of unsolicited contacts" shall be excluded from participation in Medicare. *Id.* at 42 U.S.C. § 1395m(a)(17)(C).

108. Furthermore, 42 U.S.C. § 1395m(a)(17)'s prohibition on unsolicited telemarketing by a DMEPOS supplier to Medicare beneficiaries renders a claim for payment fraudulent "whether the contact with a beneficiary is made by the supplier directly or by another party on the DME supplier's behalf." 75 Fed. Reg. 2105 (Jan. 14, 2010). "[S]upplier cannot do indirectly what they are prohibited from doing directly." *Id.*

109. The July 13, 2014 Excel sheet, *Weekly Stats_Auto Ships Orders*, which was created by D.B., demonstrates that snapshots were taken by month between September and April to assess the success of CCS's unsolicited, autodialing, telemarketing efforts by Roanoke Dialer (OBC & R/O). Table 6 does not include direct calls from CCS employees to patients.

Table 6

	Sept.	Oct.	Nov.	Dec.	Jan.	Feb.	Mar.	Apr.
Business Days	21	23	19	22	21	20	22	12
Dialer Orders	1947	1852	1737	2005	1496	1368	1512	975
Dialer Orders/Day	93	81	91	91	71	68	69	81
Dials	25177	23472	16781	21943	17005	17140	18446	10646
% Orders/Dials	8%	8%	10%	9%	9%	8%	8%	9%
Connects	5983	5479	4679	9785	4267	4569	4138	2518

% Orders/Connects	33%	34%	37%	20%	35%	30%	37%	39%
Total Roanoke Orders	2091	2101	2011	2140	1925	1738	2121	1375

110. A core portion of the Defendants' entire business model is built around unsolicited autodialing/telemarketing. As Table 6 shows, thousands of calls were made via autodialing, which equated to a significant amount of its Medicare business. These claims for payment, which were submitted for items or services generated by a prohibited solicitation are false and fraudulent under the False Claims Act.

VI. CAUSES OF ACTION

COUNT I
(False Claims Act, 31 U.S.C. § 3729(a)(1))

111. Relator repeats and realleges each allegation in each of the preceding paragraphs as if fully set forth herein.

112. At all times relevant to this Complaint, and upon information and belief continuing through the present day, Defendants knowingly presented, or caused to be presented, directly or indirectly, false and fraudulent claims for payment or approval to the United States, including claims for diabetic, wound care, urologic, ostomy and incontinence products that were either obtained through prohibited autodialing/telemarketing calls, prohibited waiver of co-pays, and/or the prohibited practices of not having the requisite PWO, patient authorization and/or not establishing medical necessity. Therefore, the payments were explicitly excluded from payment.

113. At all times relevant to this Complaint, Defendant HCM exercised both ownership and control over Defendant CCS Medical (and its related companies) and directed fraudulent practices.

114. Had the government programs known that these products were procured through

the prohibited conduct, it would not have paid or reimbursed the claims.

115. Defendants engaged in interstate commerce when the invoices, which are material, were submitted to the U.S. Government through either the United States mail and/or electronic submission via the internet.

116. As a result of these submissions, Defendants knowingly presented false and inflated claims for payment from the U.S. Government, in violation of 31 U.S.C. § 3729(a)(1). As a result, the United States has suffered damages.

117. Defendants are jointly and severally liable to the United States for treble damages under the False Claims Act, in an amount to be determined at trial, plus a civil penalty for each false claim presented or caused to be presented by the Defendants.

COUNT II
VIOLATIONS OF 31 U.S.C. § 3729(a)(1)(A)

118. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

119. This is a claim for penalties and treble damages under the False Claims Act, 31 U.S.C. § 3729 *et seq*., as amended.

120. During the relevant period, Defendants knowingly presented numerous claims for payment to the United States Government through the Federal Programs.

121. For the reasons alleged herein, many of these claims were knowingly false and fraudulent within the meaning of the FCA. More specifically, Defendants knowingly presented, and caused to be presented, to an officer and/or employee of the United States Government false and fraudulent claims for payment and approval in violation of 31 U.S.C. § 3729(a)(1)(A).

122. Defendants had actual knowledge of the falsity of these claims, or deliberately ignored or recklessly disregarded their truth or falsity, within the meaning of the FCA.

123. The United States suffered damages as a result of false claims by Defendants and is entitled to recover its losses and otherwise obtain relief available under the FCA.

COUNT III
VIOLATIONS OF 31 U.S.C. § 3729(a)(1)(B)

124. Relators re-allege and incorporate by reference the allegations contained in the preceding paragraphs of this Complaint.

125. This is a claim for penalties and treble damages under the False Claims Act, 31 U.S.C. § 3729 et seq., as amended.

126. During the past ten years, Defendant presented thousands of records and statements to the United States Government through Medicare, Medicaid, TRICARE and CHAMPVA.

127. For the reasons alleged herein, many of these records and statements were knowingly false and fraudulent within the meaning of the FCA. More specifically, Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent incentive payments/grants, as well as claims paid and approved, by the United States Government in violation of 31 U.S.C. § 3729(a)(1)(B).

128. Defendant had actual knowledge of the falsity of these statements, or deliberately ignored or recklessly disregarded their truth or falsity, within the meaning of the FCA.

129. The United States suffered damages as a result of false records and statements by Defendant and is entitled to recover its losses and otherwise obtain relief available under the FCA.

COUNT IV
VIOLATIONS OF 31 U.S.C. § 3729(a)(1)(C)

130. Relators re-allege and incorporate by reference the allegations contained in the

preceding paragraphs of this Complaint.

131. Through the acts described above and otherwise, Defendants entered into a conspiracy or conspiracies to defraud the United States by getting false and fraudulent claims allowed or paid in violation of 31 U.S.C. § 3729(a)(3), and as amended, 31 U.S.C. § 3729(a)(1)(c). Defendants also conspired to omit disclosing or to actively conceal facts which, if known, would have reduced Government obligations to Defendants or resulted in repayments from Defendants to Government programs.

COUNT V
(False Claims Act, 31 U.S.C. § 3729(a) (1) (2006)
(False Claims Act, 31 U.S.C. § 3729(a)(1)(G)
Knowing Retention of Overpayments

132. Relator repeats and re-alleges each allegation in each of the preceding paragraphs as if fully set forth herein.

133. This is a claim for penalties and treble damages under the False Claims Act, 31 U.S.C. § 3729 *et seq*., as amended.

134. During the relevant period, Defendants presented thousands of claims for payment to the Federal Programs, as well as other payors; and, knowingly retained the overpayments in violation of 31 U.S.C. § 3729(a)(1)(G) when Defendant failed to repay the money within 60 days.

135. At all times relevant to this Complaint, and upon information and belief continuing through the present day, Defendants knowingly presented, or caused to be presented, directly or indirectly, false and fraudulent claims for payment or approval to the United States, including claims for diabetic, wound care, urologic, ostomy and incontinence products that were either obtained through prohibited autodialing/telemarketing calls, prohibited waiver of co-pays, and/or the prohibited practices of not having the requisite PWO, patient authorization and/or not

establishing medical necessity. Defendants knew that their false or fraudulent claims were excluded from payment by the United States and they knowingly retained the payments.

136. For the reasons alleged herein, many of these claims were knowingly false and fraudulent within the meaning of the FCA. More specifically, Defendant knowingly withheld, and caused to be withheld, to an officer and/or employee of the United States Government false and fraudulent claims for which payment and approval had been received in violation of 31 U.S.C. § 3729(a)(1)(G) when Defendant failed to repay the money within 60 days.

137. Defendant had actual knowledge of the falsity of these claims, or deliberately ignored or recklessly disregarded their truth or falsity, within the meaning of the FCA.

138. The United States suffered damages as a result of the reverse false claims that were knowingly retained by the Defendant and is entitled to recover its losses and otherwise obtain relief available under the FCA.

COUNT VI
(60-day Rule, Affordable Care Act, Section 6402(a); 42 CFR § 401.305)

Concealing or Avoiding Obligation to Pay

139. Relator repeats and re-alleges each allegation in each of the preceding paragraphs as if fully set forth herein.

140. This is a claim for penalties and treble damages under the False Claims Act, 31 U.S.C. § 3729 *et seq*., as amended.

141. During the relevant period, Defendants presented thousands of claims for payment to the United States Government through the Federal Programs, as well as other payors.

142. At all times relevant to this Complaint, and upon information and belief continuing through the present day, Defendants knowingly presented, or caused to be presented, directly or indirectly, false and fraudulent claims for payment or approval to the United States, including

claims for diabetic, wound care, urologic, ostomy and incontinence products that were either obtained through prohibited autodialing/telemarketing calls, prohibited waiver of co-pays, and/or the prohibited practices of not having the requisite PWO, patient authorization and/or not establishing medical necessity. Defendants knew that their false or fraudulent claims were excluded from payment by the United States and they knowingly retained the payments.

143. For the reasons alleged herein, many of these claims were knowingly false and fraudulent within the meaning of the FCA. More specifically, Defendant knowingly withheld, and caused to be withheld, to an officer and/or employee of the United States Government false and fraudulent claims for which payment and approval had been received in violation of Affordable Care Act, Section 6402(a); 42 CFR § 401.305, when Defendant failed to repay the money within 60 days. Defendant had actual knowledge of the falsity of these claims, or deliberately ignored or recklessly disregarded their truth or falsity, within the meaning of the FCA.

144. The United States suffered damages as a result of false claims by the Defendant and is entitled to recover its losses and otherwise obtain relief available under the FCA.

VII. DAMAGES

145. Relator repeats and re-alleges each allegation in each of the preceding paragraphs as if fully set forth herein.

146. The FCA imposes liability on any person who knowingly presents or causes to be presented a false or fraudulent claim for payment or approval; knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim; conspires to commit a violation of the False Claims Act or knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property

to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government. 31 U.S.C. § 3729(a).

147. Prior to 2016, the last increases to the penalties for False Claims Act violations occurred on August 30, 1999 and changed the minimum from $5,000.00 to $5,500.00 and the maximum from $10,000.00 to $11,000.00, plus treble damages. 64 Fed. Reg. 47099, 47104. On August 1, 2016, the U.S. Department of Justice published Interim Final Rules, which significantly increased penalties under the False Claims Act for the first time in nearly eighteen years. Now, for violations occurring after November 2, 2015, the new minimum and maximum penalties are $10,781.00 to $21,563.00 plus treble damages. 81 Fed. Reg. 42491, 42494 (Jun. 30, 2016).

148. Here, to the best of Relator's knowledge, the Defendants submitted false claims to the government beginning in 2011.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. That Defendants be ordered to cease and desist from violating 31 U.S.C. §3729 *et seq.*; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; and the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812;

B. That this Court enter judgment against Defendants in an amount equal to treble (three times) the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each violation of 31 U.S.C. § 3729 prior to November 2, 2015;

C. That this Court enter judgment against Defendants in an amount equal to treble (three times) the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $10,781.00 and not more than $21,563.00 for each

violation of 31 U.S.C. § 3729 after November 2, 2015, pursuant to 81 Fed. Reg. 42491, 42494 (Jun. 30, 2016);

D. That Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act;

E. The Relator and the U.S. Government recover the maximum amount under the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a;

F. The Relator and the U.S. Government recover the maximum amount under the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812;

G. That Relator and his attorneys and the U.S. Government be awarded all costs of this action, including attorneys' fees and expenses; and

H. That Relator be awarded such other and further relief as this Court may deem just and proper.

CHIESA SHAHINIAN & GIANTOMASI PC
By: *s/ Lee Vartan*
Lee Vartan, Esq.
One Boland Drive
West Orange, NJ 07052
(973) 325-1500

RACHEL V. ROSE – ATTORNEY AT LAW, PLLC
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PO Box 22718
Houston, TX 77227
(713) 907-7442

Patricia D. Ryan, Esq.
(*pro hac vice* application forthcoming)
6106 Harvard Avenue
PO Box 633
Glen Echo, MD 20812
(240) 481-6284

Dated: February 8, 2019

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Relator demands a jury trial for all claims and issues so triable.

CHIESA SHAHINIAN & GIANTOMASI PC
By: *s/ Lee Vartan*
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PO Box 633
Glen Echo, MD 20812
(240) 481-6284

Dated: February 8, 2019

CERTIFICATION PURSUANT TO LOCAL RULE 11.2

In accordance with Local Civil Rule 11.2, I certify, to the best of my knowledge, that this matter in controversy is not the subject of any other action currently pending in any other court, or of any pending arbitration or administrative proceeding. I know of no other parties who should be joined in this action at this time.

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements are willfully false, I am subject to punishment.

CHIESA SHAHINIAN & GIANTOMASI PC
By: *s/ Lee Vartan*
Lee Vartan, Esq.
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(973) 325-1500

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Glen Echo, MD 20812
(240) 481-6284

Dated: February 8, 2019

Plan Name
CARESOURCE OHIO
PASSPORT HEALTH PLAN
AMERIGROUP / SSI
(blank)
HEALTHPARTNERS PA MEDICAID
AMERIGROUP DALLAS/FT WORTH TRAVIS
CIGNA
BRAVO BY ELDER HEALTH OF PA MCR HMO
MOLINA HEALTHCARE OF TX / SSI
SUPERIOR HEALTH PLAN
AMERIGROUP TX COMMUNITY CARE MCD
UNITED HEALTHCARE
AETNA PRO POS & INDEMNITY
SUPERIOR / SSI
HEALTHNET MEDICAID
CARE IMPROVEMENT PLUS MCR
CA CHILDREN SERVICES
ANTHEM BCBS OF OHIO
BLUECARE TENNCARE - VSHP
HUMANA CARESOURCE KY MEDICAID
WELLCARE OF KENTUCKY
CENCAL HEALTH
MARYLAND PHYSICIANS CARE
MOLINA HEALTHCARE OF WA MEDICAID
HIP VIP MEDICAID HMO
VIRGINIA PREMIER MEDICAID
KEYSTONE FIRST
PARTNERSHIP HEALTH PLAN MEDICAID
AETNA BETTER HEALTH
AETNA HMO/EPO
BCBS OF ILLINOIS
ANTHEM BLUE CROSS OF CA MEDICAID
TRICARE NORTH
UNITED HEALTHCARE
UNITED HEALTHCARE COMMUNITY
BCBS OF TEXAS COASTAL PPO
CENTRAL COAST ALLIANCE MEDICAID
HEALTHNET CALIFORNIA HEALTH
MEDICAL MUTUAL OF OHIO
MOLINA HEALTHCARE OF OHIO MCD
GATEWAY MEDICARE ASSURED (PA) SNP
HEALTH KEEPERS PLUS- MEDICAID
MOLINA HEALTHCARE OF WA MEDICAID
SECURE HORIZONS TEXAS HMO
AARP HEALTHCARE OPTIONS
COVENTRYCARES OF KENTUCKY

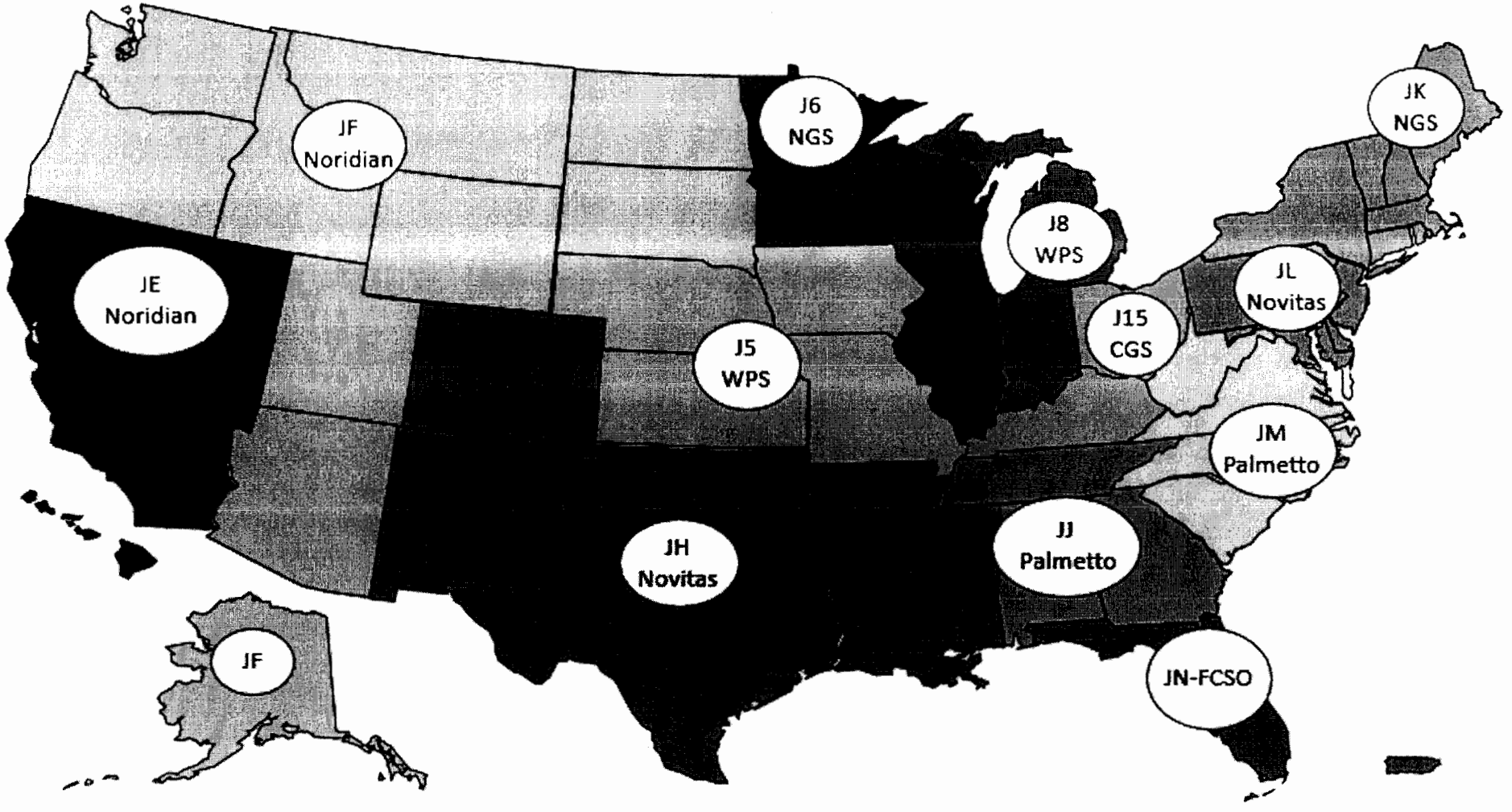
HUMANA GOLD PLUS MCR HMO
SENIOR PARTNERS MEDICARE HMO
BRAVO MID ATLANTIC MCR HMO/PPO
BCBS OF TENNESSEE
ANTHEM BCBS
EVERCARE MEDICARE ADVANTAGE SNP
HEALTH PLAN OF SAN MATEO
TRICARE FOR LIFE WPS
TRICARE SOUTH
TRIWEST UMVS
AMERIVANTAGE TX MEDICARE
ANTHEM BCBS OF KENTUCKY
ANTHEM BLUE CROSS OF CA PPO
BCBS OF FLORIDA FEDERAL
BCBS OF GEORGIA FEDERAL
BLUE SHIELD OF CA
BUCKEYE COMMUNITY HEALTH
CA CHILDREN SVCS LOS ANGELES COUNTY
CHAMP VA
EVERCARE OF TEXAS MCR SNP
GA HEALTH PARTNERSHIP
HIGHMARK BLUE SHIELD PPO
HUMANA GOLD PLUS MCR HMO
HUMANA PPO
MERIDIAN HEALTH PLAN OF IL
UNITED AMERICAN INSURANCE CO
HEALTHSPRING MEDICARE ADVANTAGE
ANTHEM BCBS OF OHIO MCR ADV PPO
HEALTH NET OF CA SENIOR
MEDICARE COMPLETE CHOICE MCR PPO
AETNA CAREMORE OF NC MANAGED CARE
AETNA US HEALTHCARE
ANTHEM BCBS OF INDIANA
ANTHEM BCBS OF VIRGINIA
ANTHEM BLUE CROSS OF CA SUPP
BCBS OF GEORGIA PPO EPO
BCBS OF TEXAS FEDERAL
CARECENTRIX BCBS FL NON MANAGED
CARECENTRIX BCBS FL OTHER-MGD
CAREFIRST BCBS OF MARYLAND
EMPIRE BCBS HMO/PPO
HEALTH PLAN OF SAN MATEO CAREADVTG
HUMANA GOLD CHOICE MEDICARE PFFS
HUMANA MEDICARE CHOICE PPO / POS
INDEPENDENCE BC PERSONAL CHOICE
MAIL HANDLERS BENEFIT PLAN
MEDICAID TX MEDSTAR OVER 21/TITLE

MOLINA HEALTHCARE OF CALIFORNIA
MONROE CTY HLTH PLN MCD - EXCELLUS
TRICARE FOR LIFE
WELLCARE OF OH MCR HMO
WELLMARK BCBS OF IOWA
SECURE HORIZONS OF CA SUTTER GROUP
BRAVO BY ELDER HEALTH OF TX MCR HMO
HEALTHSPRING MEDICARE ADVANTAGE HMO
SECURE HORIZONS CALIFORNIA HMO
MEDICARE COMPLETE MCR HMO/POS
AMERIHEALTH MERCY/NE
FIRST CARE MEDICARE ADVANTAGE HMO
AULTCARE
HIGHMARK FREEDOM BLUE PPO
AETNA MEDICARE HMO/PPO
AMERIGROUP GA COMMUNITY CARE
AMERIGROUP NJ COMMUNITY CARE
AMERIGROUP NM COMMUNITY CARE
AMERIVANTAGE MD MEDICARE ADV SNP
ANTHEM BLUE CROSS OF CA PRUDENT
BANKERS LIFE AND CASUALTY COMPANY
BCBS OF FLORIDA
BCBS OF CA
BCBS OF GEORGIA HMO/POS
BCBS OF ILLINOIS FEDERAL
BCBS OF MICHIGAN
BCBS OF MICHIGAN MCR ADVANTAGE
BCBS OF MINNESOTA
BCBS OF MISSISSIPPI FEDERAL
BCBS OF MISSOURI FEDERAL
BCBS OF OKLAHOMA
BCBS OF TEXAS SUPPLEMENTAL
BCBS OF TEXAS TRADITIONAL
BLUE CROSS OF NE PENNSYLVANIA PPO
BLUE SHIELD NORTHEASTERN NEW YORK
CAPITAL DIST PHYS HEALTH CDPHP COMM
CARE 1ST HEALTH PLAN MEDI-CAL
CARE 1ST HEALTH PLAN SENIOR HMO
CARECENTRIX BCBS FL FEDERAL PRI-MGD
CARECENTRIX BCBS FL FEDERAL SEC-MGD
CARECENTRIX TENNCARE SELECT
CAREMORE HEALTH PLAN OF CA SENIOR
CEMENT LOCAL UNION 592
CENTRAL STATES - BCBS
CHRISTIAN FIDELITY LIFE 44990
CIGNA HEALTHCARE
COMBINED INS CO OF AMERICA

CORESOURCE INC
COVENTRY CARES OF PA MCD
COVENTRY HLTH AMERICA ASSURANCE COM
COVENTRY OF IL MCR REPLACEMENT PPO
EMPIRE BLUE CROSS OF NEW YORK
EVERCARE OF NEW MEXICO
EXCELLUS BCBS CENTRAL NY/SOUTHERN
EXCELLUS BCBS ROCHESTER/UTICA
FIRST CARE / SSI
FIRST CHOICE BY SELECT HEALTH OF SC
GEISINGER GOLD MEDICARE ADV
GHI PPO
GREATWEST HEALTHCARE
HEALTH ALLIANCE
HIP HMO COMMERCIAL
HIP MONTEFIORE
HIP VIP MEDICARE HMO
HORIZON BCBS OF NEW JERSEY NASCO
HUMANA HMO / POS
HUMANA MEDICARE SUPPLEMENT
ILLNICARE
INDEPENDENT HEALTH - NY MCD
MEDICARE REGION B
MEGA LIFE AND HEALTH INSURANCE
OHIO MEDICAID - ANTHEM BCBS
PARKLAND HEALTHFIRST
PREMERA BLUE CROSS OF WA
REGENCE BLUESHIELD OF WASHINGTON
SHEET METAL WORKERS LOCAL 100
SHENANDOAH LIFE INSURANCE COMPANY
UHC
UNITED HEALTH CARE 30555
UNITED HEALTH CARE MEDICARE ADV
UNITED HEALTHCARE GROUP MCR ADV PPO
UNITED HEALTHCARE INSURANCE CO
UNITED HEALTHCARE OF RIVER VALLEY
UNITEDHEALTHCARE DUAL COMPLETE
VNSNY CHOICE TOTAL MEDICAID
WASHINGTON STATE HEALTH INS POOL
WEISS & WEXLER, P.C.
WELLCARE OF FL MCR
WELLCARE OF IL MEDICARE HMO
WELLCARE OF TX MCR
BCBS OF SOUTH CAROLINA
TODAY'S OPTIONS BY PYR LIFE PFFS
AMERIHEALTH CARITAS PENNSYLVANIA
HEALTH NET OF CA COMMERCIAL

TODAY'S OPTIONS BY AMER PROG PFFS
BCBS OF AL
FIRST CARE MEDICARE ADVANTAGE PFFS
CARESOURCE OHIO MCR REPLACEMENT
BCBS OF SOUTH CAROLINA STATE HEALTH
HEALTH NET OREGON MCR ADV HMO/PPO
BCBS OF ALABAMA
MOLINA HEALTHCARE OF TX MCR OPTIONS
ANTHEM BLUE CROSS OF CA MCR PFFS
SECURE HORIZONS MEDICAREDIRECT PFFS
HIGHMARK SECURITY BLUE HMO
Grand Total

A/B MAC Jurisdictions
as of October 2017



Local Coverage Determination (LCD): Ostomy Supplies (L33828)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
CGS Administrators, LLC	DME MAC	17013 - DME MAC J-B		Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC J-C		Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi North Carolina New Mexico Oklahoma Puerto Rico South Carolina Tennessee Texas Virginia Virgin Islands West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC J-A		Connecticut District of Columbia Delaware Massachusetts Maryland Maine New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC J-D		Alaska American Samoa Arizona California - Entire State Guam Hawaii Iowa Idaho Kansas Missouri - Entire State Montana North Dakota Nebraska Nevada Oregon South Dakota

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Utah Washington Wyoming Northern Mariana Islands

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LCD Information

Document Information

LCD ID
L33828

Original ICD-9 LCD ID
L11491
L5013
L27227
L11502

LCD Title
Ostomy Supplies

Original Effective Date
For services performed on or after 10/01/2015

Revision Effective Date
For services performed on or after 01/01/2017

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
N/A

Notice Period End Date
N/A

CMS National Coverage Policy None

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

The quantity of ostomy supplies needed by a beneficiary is determined primarily by the type of ostomy, its location, its construction, and the condition of the skin surface surrounding the stoma. There will be variation according to individual beneficiary need and their needs may vary over time. The table below lists the maximum number of items/units of service that are usually reasonable and necessary. The actual quantity needed for a particular beneficiary may be more or less than the amount listed depending on the factors that affect the frequency of barrier and pouch change.

The explanation for use of a greater quantity of supplies than the amounts listed must be clearly documented in the beneficiary's medical record. If adequate documentation is not provided when requested, the excess quantities will be denied as not reasonable and necessary.

USUAL MAXIMUM QUANTITY OF SUPPLIES:

Code	# per Month
A4357	2
A4362	20
A4364	4
A4367	1
A4369	2
A4377	10
A4381	10
A4397	4
A4402	4
A4404	10
A4405	4
A4406	4
A4414	20
A4415	20
A4416	60
A4417	60
A4418	60
A4419	60
A4420	60
A4423	60

A4424	20
A4425	20
A4426	20
A4427	20
A4429	20
A4431	20
A4432	20
A4433	20
A4434	20
A4450	40
A4452	40
A5051	60
A5052	60
A5053	60
A5054	60
A5055	31
A5056	40
A5057	40
A5061	20
A5062	20
A5063	20
A5071	20
A5072	20
A5073	20
A5081	31
A5082	1
A5083	150
A5093	10
A5121	20
A5122	20
A5126	20
A5131	1
A6216	60

Code	# per 6 Months
A4361	3
A4371	10
A4398	2
A4399	2
A4455	16
A5102	2
A5120	150

When a liquid barrier is necessary, either liquid or spray (A4369) or individual wipes or swabs (A5120) are appropriate. The use of both is not reasonable and necessary.

Beneficiaries with continent stomas may use the following means to prevent/manage drainage: stoma cap

(A5055), stoma plug (A5081), stoma absorptive cover (A5083) or gauze pads (A6216). No more than one of these types of supply would be reasonable and necessary on a given day.

Beneficiaries with urinary ostomies may use either a bag (A4357) or bottle (A5102) for drainage at night. It is not reasonable and necessary to have both.

GENERAL

A Detailed Written Order (DWO) (if applicable) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed DWO, the claim shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

REFILL REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized.

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the ordering physicians that any changed or atypical utilization is warranted.

Regardless of utilization, a supplier must not dispense more than a one (1) -month supply at a time for a beneficiary in a nursing facility and a three (3) -month supply for a beneficiary at home.

For information on tracheostomy supplies, see the Tracheostomy Care Supplies policy.

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Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph: The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

AU - Item furnished in conjunction with a urological, ostomy or tracheostomy supply.
EY - No physician or other licensed health care provider order for this item or service.

HCPCS CODES:

Group 1 Codes:

A4331 EXTENSION DRAINAGE TUBING, ANY TYPE, ANY LENGTH, WITH CONNECTOR/ADAPTOR, FOR USE WITH URINARY LEG BAG OR UROSTOMY POUCH, EACH
A4357 BEDSIDE DRAINAGE BAG, DAY OR NIGHT, WITH OR WITHOUT ANTI-REFLUX DEVICE, WITH OR WITHOUT TUBE, EACH
A4361 OSTOMY FACEPLATE, EACH
A4362 SKIN BARRIER; SOLID, 4 X 4 OR EQUIVALENT; EACH
A4363 OSTOMY CLAMP, ANY TYPE, REPLACEMENT ONLY, EACH
A4364 ADHESIVE, LIQUID OR EQUAL, ANY TYPE, PER OZ
A4366 OSTOMY VENT, ANY TYPE, EACH
A4367 OSTOMY BELT, EACH
A4368 OSTOMY FILTER, ANY TYPE, EACH
A4369 OSTOMY SKIN BARRIER, LIQUID (SPRAY, BRUSH, ETC.), PER OZ
A4371 OSTOMY SKIN BARRIER, POWDER, PER OZ
A4372 OSTOMY SKIN BARRIER, SOLID 4 X 4 OR EQUIVALENT, STANDARD WEAR, WITH BUILT-IN CONVEXITY, EACH
A4373 OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), WITH BUILT-IN CONVEXITY, ANY SIZE, EACH
A4375 OSTOMY POUCH, DRAINABLE, WITH FACEPLATE ATTACHED, PLASTIC, EACH
A4376 OSTOMY POUCH, DRAINABLE, WITH FACEPLATE ATTACHED, RUBBER, EACH
A4377 OSTOMY POUCH, DRAINABLE, FOR USE ON FACEPLATE, PLASTIC, EACH
A4378 OSTOMY POUCH, DRAINABLE, FOR USE ON FACEPLATE, RUBBER, EACH
A4379 OSTOMY POUCH, URINARY, WITH FACEPLATE ATTACHED, PLASTIC, EACH
A4380 OSTOMY POUCH, URINARY, WITH FACEPLATE ATTACHED, RUBBER, EACH
A4381 OSTOMY POUCH, URINARY, FOR USE ON FACEPLATE, PLASTIC, EACH
A4382 OSTOMY POUCH, URINARY, FOR USE ON FACEPLATE, HEAVY PLASTIC, EACH
A4383 OSTOMY POUCH, URINARY, FOR USE ON FACEPLATE, RUBBER, EACH
A4384 OSTOMY FACEPLATE EQUIVALENT, SILICONE RING, EACH
A4385 OSTOMY SKIN BARRIER, SOLID 4 X 4 OR EQUIVALENT, EXTENDED WEAR, WITHOUT BUILT-IN CONVEXITY, EACH
A4387 OSTOMY POUCH, CLOSED, WITH BARRIER ATTACHED, WITH BUILT-IN CONVEXITY (1 PIECE), EACH
A4388 OSTOMY POUCH, DRAINABLE, WITH EXTENDED WEAR BARRIER ATTACHED, (1 PIECE), EACH
A4389 OSTOMY POUCH, DRAINABLE, WITH BARRIER ATTACHED, WITH BUILT-IN CONVEXITY (1 PIECE), EACH
A4390 OSTOMY POUCH, DRAINABLE, WITH EXTENDED WEAR BARRIER ATTACHED, WITH BUILT-IN CONVEXITY (1 PIECE), EACH
A4391 OSTOMY POUCH, URINARY, WITH EXTENDED WEAR BARRIER ATTACHED (1 PIECE), EACH
A4392 OSTOMY POUCH, URINARY, WITH STANDARD WEAR BARRIER ATTACHED, WITH BUILT-IN CONVEXITY (1 PIECE), EACH
A4393 OSTOMY POUCH, URINARY, WITH EXTENDED WEAR BARRIER ATTACHED, WITH BUILT-IN CONVEXITY (1 PIECE), EACH
A4394 OSTOMY DEODORANT, WITH OR WITHOUT LUBRICANT, FOR USE IN OSTOMY POUCH, PER FLUID OUNCE
A4395 OSTOMY DEODORANT FOR USE IN OSTOMY POUCH, SOLID, PER TABLET
A4396 OSTOMY BELT WITH PERISTOMAL HERNIA SUPPORT
A4397 IRRIGATION SUPPLY; SLEEVE, EACH

A4398 OSTOMY IRRIGATION SUPPLY; BAG, EACH
A4399 OSTOMY IRRIGATION SUPPLY; CONE/CATHETER, WITH OR WITHOUT BRUSH
A4402 LUBRICANT, PER OUNCE
A4404 OSTOMY RING, EACH
A4405 OSTOMY SKIN BARRIER, NON-PECTIN BASED, PASTE, PER OUNCE
A4406 OSTOMY SKIN BARRIER, PECTIN-BASED, PASTE, PER OUNCE
A4407 OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE, OR ACCORDION), EXTENDED WEAR, WITH BUILT-IN CONVEXITY, 4 X 4 INCHES OR SMALLER, EACH
A4408 OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), EXTENDED WEAR, WITH BUILT-IN CONVEXITY, LARGER THAN 4 X 4 INCHES, EACH
A4409 OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), EXTENDED WEAR, WITHOUT BUILT-IN CONVEXITY, 4 X 4 INCHES OR SMALLER, EACH
A4410 OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), EXTENDED WEAR, WITHOUT BUILT-IN CONVEXITY, LARGER THAN 4 X 4 INCHES, EACH
A4411 OSTOMY SKIN BARRIER, SOLID 4 X 4 OR EQUIVALENT, EXTENDED WEAR, WITH BUILT-IN CONVEXITY, EACH
A4412 OSTOMY POUCH, DRAINABLE, HIGH OUTPUT, FOR USE ON A BARRIER WITH FLANGE (2 PIECE SYSTEM), WITHOUT FILTER, EACH
A4413 OSTOMY POUCH, DRAINABLE, HIGH OUTPUT, FOR USE ON A BARRIER WITH FLANGE (2 PIECE SYSTEM), WITH FILTER, EACH
A4414 OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), WITHOUT BUILT-IN CONVEXITY, 4 X 4 INCHES OR SMALLER, EACH
A4415 OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), WITHOUT BUILT-IN CONVEXITY, LARGER THAN 4 X 4 INCHES, EACH
A4416 OSTOMY POUCH, CLOSED, WITH BARRIER ATTACHED, WITH FILTER (1 PIECE), EACH
A4417 OSTOMY POUCH, CLOSED, WITH BARRIER ATTACHED, WITH BUILT-IN CONVEXITY, WITH FILTER (1 PIECE), EACH
A4418 OSTOMY POUCH, CLOSED; WITHOUT BARRIER ATTACHED, WITH FILTER (1 PIECE), EACH
A4419 OSTOMY POUCH, CLOSED; FOR USE ON BARRIER WITH NON-LOCKING FLANGE, WITH FILTER (2 PIECE), EACH
A4420 OSTOMY POUCH, CLOSED; FOR USE ON BARRIER WITH LOCKING FLANGE (2 PIECE), EACH
A4421 OSTOMY SUPPLY; MISCELLANEOUS
A4422 OSTOMY ABSORBENT MATERIAL (SHEET/PAD/CRYSTAL PACKET) FOR USE IN OSTOMY POUCH TO THICKEN LIQUID STOMAL OUTPUT, EACH
A4423 OSTOMY POUCH, CLOSED; FOR USE ON BARRIER WITH LOCKING FLANGE, WITH FILTER (2 PIECE), EACH
A4424 OSTOMY POUCH, DRAINABLE, WITH BARRIER ATTACHED, WITH FILTER (1 PIECE), EACH
A4425 OSTOMY POUCH, DRAINABLE; FOR USE ON BARRIER WITH NON-LOCKING FLANGE, WITH FILTER (2 PIECE SYSTEM), EACH
A4426 OSTOMY POUCH, DRAINABLE; FOR USE ON BARRIER WITH LOCKING FLANGE (2 PIECE SYSTEM), EACH
A4427 OSTOMY POUCH, DRAINABLE; FOR USE ON BARRIER WITH LOCKING FLANGE, WITH FILTER (2 PIECE SYSTEM), EACH
A4428 OSTOMY POUCH, URINARY, WITH EXTENDED WEAR BARRIER ATTACHED, WITH FAUCET-TYPE TAP WITH VALVE (1 PIECE), EACH
A4429 OSTOMY POUCH, URINARY, WITH BARRIER ATTACHED, WITH BUILT-IN CONVEXITY, WITH FAUCET-TYPE TAP WITH VALVE (1 PIECE), EACH
A4430 OSTOMY POUCH, URINARY, WITH EXTENDED WEAR BARRIER ATTACHED, WITH BUILT-IN CONVEXITY, WITH FAUCET-TYPE TAP WITH VALVE (1 PIECE), EACH
A4431 OSTOMY POUCH, URINARY; WITH BARRIER ATTACHED, WITH FAUCET-TYPE TAP WITH VALVE (1 PIECE), EACH
A4432 OSTOMY POUCH, URINARY; FOR USE ON BARRIER WITH NON-LOCKING FLANGE, WITH FAUCET-TYPE TAP WITH VALVE (2 PIECE), EACH
A4433 OSTOMY POUCH, URINARY; FOR USE ON BARRIER WITH LOCKING FLANGE (2 PIECE), EACH
A4434 OSTOMY POUCH, URINARY; FOR USE ON BARRIER WITH LOCKING FLANGE, WITH FAUCET-TYPE TAP WITH VALVE (2 PIECE), EACH
A4435 OSTOMY POUCH, DRAINABLE, HIGH OUTPUT, WITH EXTENDED WEAR BARRIER (ONE-PIECE SYSTEM), WITH OR WITHOUT FILTER, EACH
A4450 TAPE, NON-WATERPROOF, PER 18 SQUARE INCHES
A4452 TAPE, WATERPROOF, PER 18 SQUARE INCHES
A4455 ADHESIVE REMOVER OR SOLVENT (FOR TAPE, CEMENT OR OTHER ADHESIVE), PER OUNCE
A4456 ADHESIVE REMOVER, WIPES, ANY TYPE, EACH
A5051 OSTOMY POUCH, CLOSED; WITH BARRIER ATTACHED (1 PIECE), EACH
A5052 OSTOMY POUCH, CLOSED; WITHOUT BARRIER ATTACHED (1 PIECE), EACH

A5053	OSTOMY POUCH, CLOSED; FOR USE ON FACEPLATE, EACH
A5054	OSTOMY POUCH, CLOSED; FOR USE ON BARRIER WITH FLANGE (2 PIECE), EACH
A5055	STOMA CAP
A5056	OSTOMY POUCH, DRAINABLE, WITH EXTENDED WEAR BARRIER ATTACHED, WITH FILTER, (1 PIECE), EACH
A5057	OSTOMY POUCH, DRAINABLE, WITH EXTENDED WEAR BARRIER ATTACHED, WITH BUILT IN CONVEXITY, WITH FILTER, (1 PIECE), EACH
A5061	OSTOMY POUCH, DRAINABLE; WITH BARRIER ATTACHED, (1 PIECE), EACH
A5062	OSTOMY POUCH, DRAINABLE; WITHOUT BARRIER ATTACHED (1 PIECE), EACH
A5063	OSTOMY POUCH, DRAINABLE; FOR USE ON BARRIER WITH FLANGE (2 PIECE SYSTEM), EACH
A5071	OSTOMY POUCH, URINARY; WITH BARRIER ATTACHED (1 PIECE), EACH
A5072	OSTOMY POUCH, URINARY; WITHOUT BARRIER ATTACHED (1 PIECE), EACH
A5073	OSTOMY POUCH, URINARY; FOR USE ON BARRIER WITH FLANGE (2 PIECE), EACH
A5081	STOMA PLUG OR SEAL, ANY TYPE
A5082	CONTINENT DEVICE; CATHETER FOR CONTINENT STOMA
A5083	CONTINENT DEVICE, STOMA ABSORPTIVE COVER FOR CONTINENT STOMA
A5093	OSTOMY ACCESSORY; CONVEX INSERT
A5102	BEDSIDE DRAINAGE BOTTLE WITH OR WITHOUT TUBING, RIGID OR EXPANDABLE, EACH
A5120	SKIN BARRIER, WIPES OR SWABS, EACH
A5121	SKIN BARRIER; SOLID, 6 X 6 OR EQUIVALENT, EACH
A5122	SKIN BARRIER; SOLID, 8 X 8 OR EQUIVALENT, EACH
A5126	ADHESIVE OR NON-ADHESIVE; DISK OR FOAM PAD
A5131	APPLIANCE CLEANER, INCONTINENCE AND OSTOMY APPLIANCES, PER 16 OZ.
A6216	GAUZE, NON-IMPREGNATED, NON-STERILE, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING
A9270	NON-COVERED ITEM OR SERVICE

ICD-10 Codes that Support Medical Necessity
Group 1 Paragraph: Not specified. For ICD-10 codes relating to statutory coverage, see Policy Article.

Group 1 Codes: N/A

ICD-10 Codes that DO NOT Support Medical Necessity
Group 1 Paragraph: Not specified.

Group 1 Codes: N/A

ICD-10 Additional Information

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General Information

Associated Information
DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- Prescription (orders)
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

Refer to the Supplier Manual for additional information on documentation requirements.

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

MISCELLANEOUS

APPENDICES

UTILIZATION GUIDELINES

Refer to Coverage Indications, Limitations and/or Medical Necessity.

Sources of Information and Basis for Decision
Reserved for future use. Back to Top

Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
01/01/2017	R3	**Revision History Effective Date: 01/01/2017:** COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Standard Documentation Language Added: New reference language and directions to Standard Documentation Requirements Added: General Requirements Revised: Refill Requirements DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: General Documentation Requirements Added: New reference language and directions to Standard Documentation Requirements POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:	• Provider Education/Guidance

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
		Removed: Standard Documentation Language Added: Direction to Standard Documentation Requirements Removed: Supplier Manual reference from Miscellaneous Removed: PIM reference from Appendices RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article	
07/01/2016	R2	Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the LCDs.	• Change in Assigned States or Affiliated Contract Numbers
10/01/2015	R1	**Revsion History Effective Date: 08/01/2015** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility DOCUMENTATION REQUIREMENTS: Removed: ICD-9 references Revised: Standard Documentation Language to add who can enter date of delivery date on the POD (Note: The effective date above is not applicable to this section. These revised and added requirements are existing Medicare requirements which are now included in the LCD for easy reference) POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Language for HCPCS codes A4450, A4452 and A5120 when submitted without correct modifier	• Provider Education/Guidance

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Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A52487 - Ostomy Supplies - Policy Article A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

Related National Coverage Documents N/A

Public Version(s) Updated on 04/28/2017 with effective dates 01/01/2017 - N/A Updated on 06/07/2016 with effective dates 07/01/2016 - 12/31/2016 Updated on 06/05/2015 with effective dates 10/01/2015 - 06/30/2016 Updated on 04/04/2014 with effective dates 10/01/2015 - N/A Back to Top

Keywords

N/A Read the **LCD Disclaimer** Back to Top

END OF LOCAL COVERAGE DETERMINATION

Per the Code of Federal Regulations, 42 C.F.R § 426. 325, only those portions of the currently effective Local Coverage Determination (LCD) that are based on section 1862(a)(1)(A) of the Social Security Act, may be challenged through an acceptable complaint as described in 42 C.F.R § 426.400. Also, per 42 C.F.R § 426.325 items that are not reviewable, and therefore cannot be challenged, include the Policy Article. Please note the distinction of the documents when reviewing the materials.

Local Coverage Article:
Ostomy Supplies - Policy Article (A52487)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi North Carolina New Mexico Oklahoma Puerto Rico South Carolina Tennessee Texas Virginia Virgin Islands West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut District of Columbia Delaware Massachusetts Maryland Maine New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Iowa Idaho Kansas Missouri - Entire State Montana North Dakota Nebraska Nevada Oregon South Dakota

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Utah Washington Wyoming Northern Mariana Islands

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Article Information

General Information

Article ID
A52487

Original ICD-9 Article ID
A25375
A24140
A47237
A25313

Article Title
Ostomy Supplies - Policy Article

Original Article Effective Date
10/01/2015

Revision Effective Date
01/01/2017

Revision Ending Date
N/A

Retirement Date
N/A

Article Guidance

Article Text:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act Section 1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Ostomy supplies are covered under the Prosthetic Device benefit (Social Security Act Section 1861(s)(8)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Ostomy supplies are covered for use on a beneficiary with a surgically created opening (stoma) to divert urine, or fecal contents outside the body. Ostomy supplies are appropriately used for colostomies, ileostomies or urinary ostomies (see covered diagnosis codes below.) Use for other conditions will be denied as noncovered.

A pouch cover should be coded A9270 and will be denied as a noncovered item.

Ostomy supplies are not separately payable when a beneficiary is in a covered home health episode. Ostomy supplies must be provided by the home health agency and payment is included in the home health Medicare payment rate. It is not appropriate to bill these to the DME MAC.

Claims for tape and adhesive (A4450, A4452, A5120) that are billed without an AU modifier or another modifier indicating coverage under a different policy will be rejected as missing information.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

For quantities of supplies that exceed the usual maximum amount, there must be information in the medical record that explains the need for the increased amount. This information must be available upon request.

Claims lines for A4450, A4452 and A5120 billed without AU modifier will be rejected as missing information.

CODING GUIDELINES

BARRIERS:

A solid barrier (wafer) is an interface between the beneficiary's skin and the pouching system, has measurable thickness and has an adhesive property. Barriers may be integrated into a "1 piece" pouch, they may be manufactured with a flange and be part of a "2 piece" pouch system (skin barrier with flange, e.g., A4414), or they may be used independently (e.g., A4362), usually with a pouch that does not have its own integral skin barrier. An extended wear barrier (e.g., A4409) is a pectin-based barrier with special additives which achieve a stronger adhesive seal, resist breakdown by urine or bowel effluent, permit longer wear times between changes, and normal wear times for those who cannot achieve them with standard barriers. There are distinct codes for extended wear compared to standard wear barriers.

A barrier with built-in convexity (e.g., A4407 or A4411) is one in which an outward curve is usually achieved with plastic embedded in the barrier, allowing better protrusion of the stoma and adherence to the skin. There are distinct codes for barriers with built-in convexity compared to flat barriers.

Ostomy skin barriers greater than 4x4 inches (e.g., A4408) refer to the size of the skin barriers themselves, and not to the area of any surrounding tape.

FACEPLATES:

A faceplate is a solid interface between the beneficiary's skin and the pouch. It is usually made of plastic, rubber or encased metal. It does not have an adhesive property and there is no pectin-based or karaya material that is an integral part of a faceplate. It can be taken off the skin and reattached repeatedly. It is secured by means of a

separate adhesive and/or an elastic belt. The clips for attaching the belt are usually a part of the faceplate. There is no coding distinction between flat and convex faceplates.

The following table lists codes for faceplate systems. When supplying a pouch with faceplate attached (Column I) a claim may not be made for a component product from Column II provided at the same time.

Column I	Column II
A4375	A4361, A4377
A4376	A4361, A4378
A4379	A4361, A4381, A4382
A4380	A4361, A4383
A4416	A4366
A4417	A4366
A4418	A4366
A4419	A4366
A4423	A4366
A4424	A4366
A4425	A4366
A4427	A4366

POUCHES:

A pouch is a device for collecting stomal output. A pouch for collecting bowel effluent may be either "drainable" with an opening at the bottom through which the fecal contents are emptied, or 'closed' with a sealed bottom and no outlet. A "urinary" pouch normally incorporates anti-reflux devices and a tap or spigot to empty the urine contents.

A pouch "with barrier attached" is one type of "1 piece" system in which a solid barrier is part of the pouch. There are distinct codes for 1-piece pouches with convex barriers and extended wear barriers (see "Barriers").

A pouch "without barrier attached" is a pouch with or without a thin adhesive coating that is applied either directly to the skin or to a separate barrier. It is also described as a "1 piece" system.

A pouch, which is part of a "2 piece" system, has a flange, which enables it to be coupled to a skin barrier with flange.

A pouch "with faceplate attached" or "for use on a faceplate" is generally rubber or heavy plastic. It is drainable, cleanable, and reusable for periods of weeks to months, depending on the product.

A "high output" pouch (A4412, A4413, A4435) has a capacity of greater than or equal to 0.75 liters, is drainable with a large bore solid spout with cap or plug, and is either part of a 2 piece system (A4412, A4413) or a single-piece system (A4435).

Codes for pouches with filters (e.g., A4416) describe pouches that have an opening which allows venting of trapped gas. They typically include materials such as charcoal to deodorize the vented gas. Code A4368 describes replacement filter material.

Code A4366 describes a separate ostomy vent that can be added by the beneficiary to a pouch to allow the release of gas. This code must not be used for pouches in which a vent with a filter is incorporated in the pouch by the manufacturer. Those products are described by the codes for ostomy pouches with a filter (A4416-A4419, A4423-A4425, A4427).

Absorbent material (A4422) that is added to the ostomy pouch may come as sheets, pads or crystals.

An ostomy pouch with faucet-type tap with valve (e.g., A4429) has a valve for draining urine.

A locking flange (e.g., A4420) is a lever type flange locking mechanism. It differs from simple push-on pouch securing mechanisms. The mechanism may be incorporated either in the pouch flange or skin barrier flange (2 piece system).

PASTES:

A paste is used as a protective layer and sealant beneath ostomy appliances, and is applied directly on the skin. It may be primarily pectin based (A4406), or non-pectin based, e.g., karaya (A4405).

MISCELLANEOUS:

Code A4400 (Ostomy irrigation set) is not valid for claim submission. If an irrigation kit is supplied, the individual components should be billed using individual codes, A4397, A4398, and A4399.

Ostomy clamps (A4363) are used with drainable pouches and are not used with urinary pouches. Ostomy clamps are only payable when ordered as a replacement. Claims for ostomy clamps billed with ostomy pouches will be denied as not separately payable with ostomy pouches.

When codes A4450, A4452, and A5120 are used with ostomy supplies, they must be billed with the AU modifier. For this policy, codes A4450, A4452, and A5120 are the only codes for which the AU modifier may be used.

Suppliers should contact the Pricing, Data Analysis, and Coding (PDAC) contractor for guidance on the correct coding of these items. Back to Top

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes N/A

ICD-10 Codes that are Covered
Group 1 Paragraph:
The presence of an ICD-10 code listed in this section is not sufficient by itself to assure coverage. Refer to the Non-Medical Necessity Coverage and Payment Rules section for other coverage criteria and payment information.

Group 1 Codes:
ICD-10 Codes that are covered Information Table

Code	Description
K94.00	Colostomy complication, unspecified

Code	Description
K94.03	Colostomy malfunction
K94.10	Enterostomy complication, unspecified
K94.13	Enterostomy malfunction
Z43.2	Encounter for attention to ileostomy
Z43.3	Encounter for attention to colostomy
Z43.6	Encounter for attention to other artificial openings of urinary tract
Z93.2	Ileostomy status
Z93.3	Colostomy status
Z93.6	Other artificial openings of urinary tract status

ICD-10 Codes that are Not Covered
Group 1 Paragraph:
For all HCPCS codes except A4331, A4364, A4402, A4450, A4452, A4455, A4456, A5102, A5120. All ICD-10 codes that are not specified in the previous section.

Group 1 Codes: N/A
ICD-10 that are not Covered Information Table
Code Description

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation
01/01/2017	R3	**Revision Effective Date: 01/01/2017** POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Billing Directions RELATED LOCAL COVERAGE DOCUMENTS: Added: Standard Documentation Language article
07/01/2016	R2	Effective July 1, 2016 oversight for DME MAC Articles is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the Articles.
10/01/2015	R1	**Revision Effective Date: 08/01/2015** NON-MEDICAL NECESSITY AND PAYMENT RULES: Removed: ICD-9 references Revised: Language for HCPCS codes A4450, A4452, A5120 when submitted without correct modifier

Back to Top **Related Local Coverage Document(s)** Article(s) A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs LCD(s) L33828 - Ostomy Supplies

Related National Coverage Document(s) N/A

Statutory Requirements URL(s) N/A

Rules and Regulations URL(s) N/A

CMS Manual Explanations URL(s) N/A

Other URL(s) N/A

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Keywords

N/A Read the **Article Disclaimer** Back to Top

Local Coverage Determination (LCD): Ostomy Supplies (L33828)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi North Carolina New Mexico Oklahoma Puerto Rico South Carolina Tennessee Texas Virginia Virgin Islands West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut District of Columbia Delaware Massachusetts Maryland Maine New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Iowa Idaho Kansas Missouri - Entire State Montana North Dakota Nebraska Nevada Oregon South Dakota

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Utah Washington Wyoming Northern Mariana Islands

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LCD Information

Document Information

LCD ID
L33828

Original ICD-9 LCD ID
L11491
L5013
L27227
L11502

LCD Title
Ostomy Supplies

Original Effective Date
For services performed on or after 10/01/2015

Revision Effective Date
For services performed on or after 01/01/2017

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
N/A

Notice Period End Date
N/A

CMS National Coverage Policy None

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

The quantity of ostomy supplies needed by a beneficiary is determined primarily by the type of ostomy, its location, its construction, and the condition of the skin surface surrounding the stoma. There will be variation according to individual beneficiary need and their needs may vary over time. The table below lists the maximum number of items/units of service that are usually reasonable and necessary. The actual quantity needed for a particular beneficiary may be more or less than the amount listed depending on the factors that affect the frequency of barrier and pouch change.

The explanation for use of a greater quantity of supplies than the amounts listed must be clearly documented in the beneficiary's medical record. If adequate documentation is not provided when requested, the excess quantities will be denied as not reasonable and necessary.

USUAL MAXIMUM QUANTITY OF SUPPLIES:

Code	# per Month
A4357	2
A4362	20
A4364	4
A4367	1
A4369	2
A4377	10
A4381	10
A4397	4
A4402	4
A4404	10
A4405	4
A4406	4
A4414	20
A4415	20
A4416	60
A4417	60
A4418	60
A4419	60
A4420	60
A4423	60

A4424	20
A4425	20
A4426	20
A4427	20
A4429	20
A4431	20
A4432	20
A4433	20
A4434	20
A4450	40
A4452	40
A5051	60
A5052	60
A5053	60
A5054	60
A5055	31
A5056	40
A5057	40
A5061	20
A5062	20
A5063	20
A5071	20
A5072	20
A5073	20
A5081	31
A5082	1
A5083	150
A5093	10
A5121	20
A5122	20
A5126	20
A5131	1
A6216	60

Code	# per 6 Months
A4361	3
A4371	10
A4398	2
A4399	2
A4455	16
A5102	2
A5120	150

When a liquid barrier is necessary, either liquid or spray (A4369) or individual wipes or swabs (A5120) are appropriate. The use of both is not reasonable and necessary.

Beneficiaries with continent stomas may use the following means to prevent/manage drainage: stoma cap

(A5055), stoma plug (A5081), stoma absorptive cover (A5083) or gauze pads (A6216). No more than one of these types of supply would be reasonable and necessary on a given day.

Beneficiaries with urinary ostomies may use either a bag (A4357) or bottle (A5102) for drainage at night. It is not reasonable and necessary to have both.

GENERAL

A Detailed Written Order (DWO) (if applicable) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed DWO, the claim shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

REFILL REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized.

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the ordering physicians that any changed or atypical utilization is warranted.

Regardless of utilization, a supplier must not dispense more than a one (1) -month supply at a time for a beneficiary in a nursing facility and a three (3) -month supply for a beneficiary at home.

For information on tracheostomy supplies, see the Tracheostomy Care Supplies policy.

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Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph: The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

AU - Item furnished in conjunction with a urological, ostomy or tracheostomy supply.
EY - No physician or other licensed health care provider order for this item or service.

HCPCS CODES:

Group 1 Codes:

A4331	EXTENSION DRAINAGE TUBING, ANY TYPE, ANY LENGTH, WITH CONNECTOR/ADAPTOR, FOR USE WITH URINARY LEG BAG OR UROSTOMY POUCH, EACH
A4357	BEDSIDE DRAINAGE BAG, DAY OR NIGHT, WITH OR WITHOUT ANTI-REFLUX DEVICE, WITH OR WITHOUT TUBE, EACH
A4361	OSTOMY FACEPLATE, EACH
A4362	SKIN BARRIER; SOLID, 4 X 4 OR EQUIVALENT; EACH
A4363	OSTOMY CLAMP, ANY TYPE, REPLACEMENT ONLY, EACH
A4364	ADHESIVE, LIQUID OR EQUAL, ANY TYPE, PER OZ
A4366	OSTOMY VENT, ANY TYPE, EACH
A4367	OSTOMY BELT, EACH
A4368	OSTOMY FILTER, ANY TYPE, EACH
A4369	OSTOMY SKIN BARRIER, LIQUID (SPRAY, BRUSH, ETC.), PER OZ
A4371	OSTOMY SKIN BARRIER, POWDER, PER OZ
A4372	OSTOMY SKIN BARRIER, SOLID 4 X 4 OR EQUIVALENT, STANDARD WEAR, WITH BUILT-IN CONVEXITY, EACH
A4373	OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), WITH BUILT-IN CONVEXITY, ANY SIZE, EACH
A4375	OSTOMY POUCH, DRAINABLE, WITH FACEPLATE ATTACHED, PLASTIC, EACH
A4376	OSTOMY POUCH, DRAINABLE, WITH FACEPLATE ATTACHED, RUBBER, EACH
A4377	OSTOMY POUCH, DRAINABLE, FOR USE ON FACEPLATE, PLASTIC, EACH
A4378	OSTOMY POUCH, DRAINABLE, FOR USE ON FACEPLATE, RUBBER, EACH
A4379	OSTOMY POUCH, URINARY, WITH FACEPLATE ATTACHED, PLASTIC, EACH
A4380	OSTOMY POUCH, URINARY, WITH FACEPLATE ATTACHED, RUBBER, EACH
A4381	OSTOMY POUCH, URINARY, FOR USE ON FACEPLATE, PLASTIC, EACH
A4382	OSTOMY POUCH, URINARY, FOR USE ON FACEPLATE, HEAVY PLASTIC, EACH
A4383	OSTOMY POUCH, URINARY, FOR USE ON FACEPLATE, RUBBER, EACH
A4384	OSTOMY FACEPLATE EQUIVALENT, SILICONE RING, EACH
A4385	OSTOMY SKIN BARRIER, SOLID 4 X 4 OR EQUIVALENT, EXTENDED WEAR, WITHOUT BUILT-IN CONVEXITY, EACH
A4387	OSTOMY POUCH, CLOSED, WITH BARRIER ATTACHED, WITH BUILT-IN CONVEXITY (1 PIECE), EACH
A4388	OSTOMY POUCH, DRAINABLE, WITH EXTENDED WEAR BARRIER ATTACHED, (1 PIECE), EACH
A4389	OSTOMY POUCH, DRAINABLE, WITH BARRIER ATTACHED, WITH BUILT-IN CONVEXITY (1 PIECE), EACH
A4390	OSTOMY POUCH, DRAINABLE, WITH EXTENDED WEAR BARRIER ATTACHED, WITH BUILT-IN CONVEXITY (1 PIECE), EACH
A4391	OSTOMY POUCH, URINARY, WITH EXTENDED WEAR BARRIER ATTACHED (1 PIECE), EACH
A4392	OSTOMY POUCH, URINARY, WITH STANDARD WEAR BARRIER ATTACHED, WITH BUILT-IN CONVEXITY (1 PIECE), EACH
A4393	OSTOMY POUCH, URINARY, WITH EXTENDED WEAR BARRIER ATTACHED, WITH BUILT-IN CONVEXITY (1 PIECE), EACH
A4394	OSTOMY DEODORANT, WITH OR WITHOUT LUBRICANT, FOR USE IN OSTOMY POUCH, PER FLUID OUNCE
A4395	OSTOMY DEODORANT FOR USE IN OSTOMY POUCH, SOLID, PER TABLET
A4396	OSTOMY BELT WITH PERISTOMAL HERNIA SUPPORT
A4397	IRRIGATION SUPPLY; SLEEVE, EACH

A4398 OSTOMY IRRIGATION SUPPLY; BAG, EACH
A4399 OSTOMY IRRIGATION SUPPLY; CONE/CATHETER, WITH OR WITHOUT BRUSH
A4402 LUBRICANT, PER OUNCE
A4404 OSTOMY RING, EACH
A4405 OSTOMY SKIN BARRIER, NON-PECTIN BASED, PASTE, PER OUNCE
A4406 OSTOMY SKIN BARRIER, PECTIN-BASED, PASTE, PER OUNCE
A4407 OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE, OR ACCORDION), EXTENDED WEAR, WITH BUILT-IN CONVEXITY, 4 X 4 INCHES OR SMALLER, EACH
A4408 OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), EXTENDED WEAR, WITH BUILT-IN CONVEXITY, LARGER THAN 4 X 4 INCHES, EACH
A4409 OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), EXTENDED WEAR, WITHOUT BUILT-IN CONVEXITY, 4 X 4 INCHES OR SMALLER, EACH
A4410 OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), EXTENDED WEAR, WITHOUT BUILT-IN CONVEXITY, LARGER THAN 4 X 4 INCHES, EACH
A4411 OSTOMY SKIN BARRIER, SOLID 4 X 4 OR EQUIVALENT, EXTENDED WEAR, WITH BUILT-IN CONVEXITY, EACH
A4412 OSTOMY POUCH, DRAINABLE, HIGH OUTPUT, FOR USE ON A BARRIER WITH FLANGE (2 PIECE SYSTEM), WITHOUT FILTER, EACH
A4413 OSTOMY POUCH, DRAINABLE, HIGH OUTPUT, FOR USE ON A BARRIER WITH FLANGE (2 PIECE SYSTEM), WITH FILTER, EACH
A4414 OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), WITHOUT BUILT-IN CONVEXITY, 4 X 4 INCHES OR SMALLER, EACH
A4415 OSTOMY SKIN BARRIER, WITH FLANGE (SOLID, FLEXIBLE OR ACCORDION), WITHOUT BUILT-IN CONVEXITY, LARGER THAN 4 X 4 INCHES, EACH
A4416 OSTOMY POUCH, CLOSED, WITH BARRIER ATTACHED, WITH FILTER (1 PIECE), EACH
A4417 OSTOMY POUCH, CLOSED, WITH BARRIER ATTACHED, WITH BUILT-IN CONVEXITY, WITH FILTER (1 PIECE), EACH
A4418 OSTOMY POUCH, CLOSED; WITHOUT BARRIER ATTACHED, WITH FILTER (1 PIECE), EACH
A4419 OSTOMY POUCH, CLOSED; FOR USE ON BARRIER WITH NON-LOCKING FLANGE, WITH FILTER (2 PIECE), EACH
A4420 OSTOMY POUCH, CLOSED; FOR USE ON BARRIER WITH LOCKING FLANGE (2 PIECE), EACH
A4421 OSTOMY SUPPLY; MISCELLANEOUS
A4422 OSTOMY ABSORBENT MATERIAL (SHEET/PAD/CRYSTAL PACKET) FOR USE IN OSTOMY POUCH TO THICKEN LIQUID STOMAL OUTPUT, EACH
A4423 OSTOMY POUCH, CLOSED; FOR USE ON BARRIER WITH LOCKING FLANGE, WITH FILTER (2 PIECE), EACH
A4424 OSTOMY POUCH, DRAINABLE, WITH BARRIER ATTACHED, WITH FILTER (1 PIECE), EACH
A4425 OSTOMY POUCH, DRAINABLE; FOR USE ON BARRIER WITH NON-LOCKING FLANGE, WITH FILTER (2 PIECE SYSTEM), EACH
A4426 OSTOMY POUCH, DRAINABLE; FOR USE ON BARRIER WITH LOCKING FLANGE (2 PIECE SYSTEM), EACH
A4427 OSTOMY POUCH, DRAINABLE; FOR USE ON BARRIER WITH LOCKING FLANGE, WITH FILTER (2 PIECE SYSTEM), EACH
A4428 OSTOMY POUCH, URINARY, WITH EXTENDED WEAR BARRIER ATTACHED, WITH FAUCET-TYPE TAP WITH VALVE (1 PIECE), EACH
A4429 OSTOMY POUCH, URINARY, WITH BARRIER ATTACHED, WITH BUILT-IN CONVEXITY, WITH FAUCET-TYPE TAP WITH VALVE (1 PIECE), EACH
A4430 OSTOMY POUCH, URINARY, WITH EXTENDED WEAR BARRIER ATTACHED, WITH BUILT-IN CONVEXITY, WITH FAUCET-TYPE TAP WITH VALVE (1 PIECE), EACH
A4431 OSTOMY POUCH, URINARY; WITH BARRIER ATTACHED, WITH FAUCET-TYPE TAP WITH VALVE (1 PIECE), EACH
A4432 OSTOMY POUCH, URINARY; FOR USE ON BARRIER WITH NON-LOCKING FLANGE, WITH FAUCET-TYPE TAP WITH VALVE (2 PIECE), EACH
A4433 OSTOMY POUCH, URINARY; FOR USE ON BARRIER WITH LOCKING FLANGE (2 PIECE), EACH
A4434 OSTOMY POUCH, URINARY; FOR USE ON BARRIER WITH LOCKING FLANGE, WITH FAUCET-TYPE TAP WITH VALVE (2 PIECE), EACH
A4435 OSTOMY POUCH, DRAINABLE, HIGH OUTPUT, WITH EXTENDED WEAR BARRIER (ONE-PIECE SYSTEM), WITH OR WITHOUT FILTER, EACH
A4450 TAPE, NON-WATERPROOF, PER 18 SQUARE INCHES
A4452 TAPE, WATERPROOF, PER 18 SQUARE INCHES
A4455 ADHESIVE REMOVER OR SOLVENT (FOR TAPE, CEMENT OR OTHER ADHESIVE), PER OUNCE
A4456 ADHESIVE REMOVER, WIPES, ANY TYPE, EACH
A5051 OSTOMY POUCH, CLOSED; WITH BARRIER ATTACHED (1 PIECE), EACH
A5052 OSTOMY POUCH, CLOSED; WITHOUT BARRIER ATTACHED (1 PIECE), EACH

A5053	OSTOMY POUCH, CLOSED; FOR USE ON FACEPLATE, EACH
A5054	OSTOMY POUCH, CLOSED; FOR USE ON BARRIER WITH FLANGE (2 PIECE), EACH
A5055	STOMA CAP
A5056	OSTOMY POUCH, DRAINABLE, WITH EXTENDED WEAR BARRIER ATTACHED, WITH FILTER, (1 PIECE), EACH
A5057	OSTOMY POUCH, DRAINABLE, WITH EXTENDED WEAR BARRIER ATTACHED, WITH BUILT IN CONVEXITY, WITH FILTER, (1 PIECE), EACH
A5061	OSTOMY POUCH, DRAINABLE; WITH BARRIER ATTACHED, (1 PIECE), EACH
A5062	OSTOMY POUCH, DRAINABLE; WITHOUT BARRIER ATTACHED (1 PIECE), EACH
A5063	OSTOMY POUCH, DRAINABLE; FOR USE ON BARRIER WITH FLANGE (2 PIECE SYSTEM), EACH
A5071	OSTOMY POUCH, URINARY; WITH BARRIER ATTACHED (1 PIECE), EACH
A5072	OSTOMY POUCH, URINARY; WITHOUT BARRIER ATTACHED (1 PIECE), EACH
A5073	OSTOMY POUCH, URINARY; FOR USE ON BARRIER WITH FLANGE (2 PIECE), EACH
A5081	STOMA PLUG OR SEAL, ANY TYPE
A5082	CONTINENT DEVICE; CATHETER FOR CONTINENT STOMA
A5083	CONTINENT DEVICE, STOMA ABSORPTIVE COVER FOR CONTINENT STOMA
A5093	OSTOMY ACCESSORY; CONVEX INSERT
A5102	BEDSIDE DRAINAGE BOTTLE WITH OR WITHOUT TUBING, RIGID OR EXPANDABLE, EACH
A5120	SKIN BARRIER, WIPES OR SWABS, EACH
A5121	SKIN BARRIER; SOLID, 6 X 6 OR EQUIVALENT, EACH
A5122	SKIN BARRIER; SOLID, 8 X 8 OR EQUIVALENT, EACH
A5126	ADHESIVE OR NON-ADHESIVE; DISK OR FOAM PAD
A5131	APPLIANCE CLEANER, INCONTINENCE AND OSTOMY APPLIANCES, PER 16 OZ.
A6216	GAUZE, NON-IMPREGNATED, NON-STERILE, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING
A9270	NON-COVERED ITEM OR SERVICE

ICD-10 Codes that Support Medical Necessity
Group 1 Paragraph: Not specified. For ICD-10 codes relating to statutory coverage, see Policy Article.

Group 1 Codes: N/A

ICD-10 Codes that DO NOT Support Medical Necessity
Group 1 Paragraph: Not specified.

Group 1 Codes: N/A

ICD-10 Additional Information

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General Information

Associated Information
DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- Prescription (orders)
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

Refer to the Supplier Manual for additional information on documentation requirements.

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

MISCELLANEOUS

APPENDICES

UTILIZATION GUIDELINES

Refer to Coverage Indications, Limitations and/or Medical Necessity.

Sources of Information and Basis for Decision
Reserved for future use. Back to Top

Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
01/01/2017	R3	**Revision History Effective Date: 01/01/2017:** COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Standard Documentation Language Added: New reference language and directions to Standard Documentation Requirements Added: General Requirements Revised: Refill Requirements DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: General Documentation Requirements Added: New reference language and directions to Standard Documentation Requirements POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:	• Provider Education/Guidance

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
		Removed: Standard Documentation Language Added: Direction to Standard Documentation Requirements Removed: Supplier Manual reference from Miscellaneous Removed: PIM reference from Appendices RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article	
07/01/2016	R2	Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the LCDs.	• Change in Assigned States or Affiliated Contract Numbers
10/01/2015	R1	**Revsion History Effective Date: 08/01/2015** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility DOCUMENTATION REQUIREMENTS: Removed: ICD-9 references Revised: Standard Documentation Language to add who can enter date of delivery date on the POD (Note: The effective date above is not applicable to this section. These revised and added requirements are existing Medicare requirements which are now included in the LCD for easy reference) POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Language for HCPCS codes A4450, A4452 and A5120 when submitted without correct modifier	• Provider Education/Guidance

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Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A52487 - Ostomy Supplies - Policy Article A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

Related National Coverage Documents N/A

Public Version(s) Updated on 04/28/2017 with effective dates 01/01/2017 - N/A Updated on 06/07/2016 with effective dates 07/01/2016 - 12/31/2016 Updated on 06/05/2015 with effective dates 10/01/2015 - 06/30/2016 Updated on 04/04/2014 with effective dates 10/01/2015 - N/A Back to Top

Keywords

N/A Read the **LCD Disclaimer** Back to Top

END OF LOCAL COVERAGE DETERMINATION

Per the Code of Federal Regulations, 42 C.F.R § 426. 325, only those portions of the currently effective Local Coverage Determination (LCD) that are based on section 1862(a)(1)(A) of the Social Security Act, may be challenged through an acceptable complaint as described in 42 C.F.R § 426.400. Also, per 42 C.F.R § 426.325 items that are not reviewable, and therefore cannot be challenged, include the Policy Article. Please note the distinction of the documents when reviewing the materials.

Local Coverage Article: Ostomy Supplies - Policy Article (A52487)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi North Carolina New Mexico Oklahoma Puerto Rico South Carolina Tennessee Texas Virginia Virgin Islands West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut District of Columbia Delaware Massachusetts Maryland Maine New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Iowa Idaho Kansas Missouri - Entire State Montana North Dakota Nebraska Nevada Oregon South Dakota

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Utah Washington Wyoming Northern Mariana Islands

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Article Information

General Information

Article ID
A52487

Original ICD-9 Article ID
A25375
A24140
A47237
A25313

Article Title
Ostomy Supplies - Policy Article

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Original Article Effective Date
10/01/2015

Revision Effective Date
01/01/2017

Revision Ending Date
N/A

Retirement Date
N/A

Article Guidance

Article Text:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act Section 1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Ostomy supplies are covered under the Prosthetic Device benefit (Social Security Act Section 1861(s)(8)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Ostomy supplies are covered for use on a beneficiary with a surgically created opening (stoma) to divert urine, or fecal contents outside the body. Ostomy supplies are appropriately used for colostomies, ileostomies or urinary ostomies (see covered diagnosis codes below.) Use for other conditions will be denied as noncovered.

A pouch cover should be coded A9270 and will be denied as a noncovered item.

Ostomy supplies are not separately payable when a beneficiary is in a covered home health episode. Ostomy supplies must be provided by the home health agency and payment is included in the home health Medicare payment rate. It is not appropriate to bill these to the DME MAC.

Claims for tape and adhesive (A4450, A4452, A5120) that are billed without an AU modifier or another modifier indicating coverage under a different policy will be rejected as missing information.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

For quantities of supplies that exceed the usual maximum amount, there must be information in the medical record that explains the need for the increased amount. This information must be available upon request.

Claims lines for A4450, A4452 and A5120 billed without AU modifier will be rejected as missing information.

CODING GUIDELINES

BARRIERS:

A solid barrier (wafer) is an interface between the beneficiary's skin and the pouching system, has measurable thickness and has an adhesive property. Barriers may be integrated into a "1 piece" pouch, they may be manufactured with a flange and be part of a "2 piece" pouch system (skin barrier with flange, e.g., A4414), or they may be used independently (e.g., A4362), usually with a pouch that does not have its own integral skin barrier. An extended wear barrier (e.g., A4409) is a pectin-based barrier with special additives which achieve a stronger adhesive seal, resist breakdown by urine or bowel effluent, permit longer wear times between changes, and normal wear times for those who cannot achieve them with standard barriers. There are distinct codes for extended wear compared to standard wear barriers.

A barrier with built-in convexity (e.g., A4407 or A4411) is one in which an outward curve is usually achieved with plastic embedded in the barrier, allowing better protrusion of the stoma and adherence to the skin. There are distinct codes for barriers with built-in convexity compared to flat barriers.

Ostomy skin barriers greater than 4x4 inches (e.g., A4408) refer to the size of the skin barriers themselves, and not to the area of any surrounding tape.

FACEPLATES:

A faceplate is a solid interface between the beneficiary's skin and the pouch. It is usually made of plastic, rubber or encased metal. It does not have an adhesive property and there is no pectin-based or karaya material that is an integral part of a faceplate. It can be taken off the skin and reattached repeatedly. It is secured by means of a

separate adhesive and/or an elastic belt. The clips for attaching the belt are usually a part of the faceplate. There is no coding distinction between flat and convex faceplates.

The following table lists codes for faceplate systems. When supplying a pouch with faceplate attached (Column I) a claim may not be made for a component product from Column II provided at the same time.

Column I	Column II
A4375	A4361, A4377
A4376	A4361, A4378
A4379	A4361, A4381, A4382
A4380	A4361, A4383
A4416	A4366
A4417	A4366
A4418	A4366
A4419	A4366
A4423	A4366
A4424	A4366
A4425	A4366
A4427	A4366

POUCHES:

A pouch is a device for collecting stomal output. A pouch for collecting bowel effluent may be either "drainable" with an opening at the bottom through which the fecal contents are emptied, or 'closed' with a sealed bottom and no outlet. A "urinary" pouch normally incorporates anti-reflux devices and a tap or spigot to empty the urine contents.

A pouch "with barrier attached" is one type of "1 piece" system in which a solid barrier is part of the pouch. There are distinct codes for 1-piece pouches with convex barriers and extended wear barriers (see "Barriers").

A pouch "without barrier attached" is a pouch with or without a thin adhesive coating that is applied either directly to the skin or to a separate barrier. It is also described as a "1 piece" system.

A pouch, which is part of a "2 piece" system, has a flange, which enables it to be coupled to a skin barrier with flange.

A pouch "with faceplate attached" or "for use on a faceplate" is generally rubber or heavy plastic. It is drainable, cleanable, and reusable for periods of weeks to months, depending on the product.

A "high output" pouch (A4412, A4413, A4435) has a capacity of greater than or equal to 0.75 liters, is drainable with a large bore solid spout with cap or plug, and is either part of a 2 piece system (A4412, A4413) or a single-piece system (A4435).

Codes for pouches with filters (e.g., A4416) describe pouches that have an opening which allows venting of trapped gas. They typically include materials such as charcoal to deodorize the vented gas. Code A4368 describes replacement filter material.

Code A4366 describes a separate ostomy vent that can be added by the beneficiary to a pouch to allow the release of gas. This code must not be used for pouches in which a vent with a filter is incorporated in the pouch by the manufacturer. Those products are described by the codes for ostomy pouches with a filter (A4416-A4419, A4423-A4425, A4427).

Absorbent material (A4422) that is added to the ostomy pouch may come as sheets, pads or crystals.

An ostomy pouch with faucet-type tap with valve (e.g., A4429) has a valve for draining urine.

A locking flange (e.g., A4420) is a lever type flange locking mechanism. It differs from simple push-on pouch securing mechanisms. The mechanism may be incorporated either in the pouch flange or skin barrier flange (2 piece system).

PASTES:

A paste is used as a protective layer and sealant beneath ostomy appliances, and is applied directly on the skin. It may be primarily pectin based (A4406), or non-pectin based, e.g., karaya (A4405).

MISCELLANEOUS:

Code A4400 (Ostomy irrigation set) is not valid for claim submission. If an irrigation kit is supplied, the individual components should be billed using individual codes, A4397, A4398, and A4399.

Ostomy clamps (A4363) are used with drainable pouches and are not used with urinary pouches. Ostomy clamps are only payable when ordered as a replacement. Claims for ostomy clamps billed with ostomy pouches will be denied as not separately payable with ostomy pouches.

When codes A4450, A4452, and A5120 are used with ostomy supplies, they must be billed with the AU modifier. For this policy, codes A4450, A4452, and A5120 are the only codes for which the AU modifier may be used.

Suppliers should contact the Pricing, Data Analysis, and Coding (PDAC) contractor for guidance on the correct coding of these items. Back to Top

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes N/A

ICD-10 Codes that are Covered
Group 1 Paragraph:
The presence of an ICD-10 code listed in this section is not sufficient by itself to assure coverage. Refer to the Non-Medical Necessity Coverage and Payment Rules section for other coverage criteria and payment information.

Group 1 Codes:
ICD-10 Codes that are covered Information Table

Code	Description
K94.00	Colostomy complication, unspecified

Code	Description
K94.03	Colostomy malfunction
K94.10	Enterostomy complication, unspecified
K94.13	Enterostomy malfunction
Z43.2	Encounter for attention to ileostomy
Z43.3	Encounter for attention to colostomy
Z43.6	Encounter for attention to other artificial openings of urinary tract
Z93.2	Ileostomy status
Z93.3	Colostomy status
Z93.6	Other artificial openings of urinary tract status

ICD-10 Codes that are Not Covered
Group 1 Paragraph:
For all HCPCS codes except A4331, A4364, A4402, A4450, A4452, A4455, A4456, A5102, A5120. All ICD-10 codes that are not specified in the previous section.

Group 1 Codes: N/A
ICD-10 that are not Covered Information Table
Code Description

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation
		Revision Effective Date: 01/01/2017
01/01/2017	R3	POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Billing Directions RELATED LOCAL COVERAGE DOCUMENTS: Added: Standard Documentation Language article
07/01/2016	R2	Effective July 1, 2016 oversight for DME MAC Articles is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the Articles.
		Revision Effective Date: 08/01/2015
10/01/2015	R1	NON-MEDICAL NECESSITY AND PAYMENT RULES: Removed: ICD-9 references Revised: Language for HCPCS codes A4450, A4452, A5120 when submitted without correct modifier

Back to Top **Related Local Coverage Document(s)** Article(s) A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs LCD(s) L33828 - Ostomy Supplies

Related National Coverage Document(s) N/A

Statutory Requirements URL(s) N/A

Rules and Regulations URL(s) N/A

CMS Manual Explanations URL(s) N/A

Other URL(s) N/A

Public Version(s) Updated on 04/28/2017 with effective dates 01/01/2017 - N/A Updated on 06/07/2016 with effective dates 07/01/2016 - N/A Updated on 06/05/2015 with effective dates 10/01/2015 - N/A Updated on 04/04/2014 with effective dates 10/01/2015 - N/A Back to Top

Keywords

N/A Read the **Article Disclaimer** Back to Top

CCS Medical Awarded Medicare Contract

CCS Medical Is Named Winner in National Competitive Bidding Program

NEWS PROVIDED BY
CCS Medical →
Apr 11, 2013, 08:01 ET

FARMERS BRANCH, Texas, April 11, 2013 /PRNewswire/ -- CCS Medical, a leading provider of home delivery medical equipment and supplies, announced today that it has been named a winner in the national Competitive Bidding Program of the Centers for Medicare & Medicaid Services (CMS).

(Logo: http://photos.prnewswire.com/prnh/20130306/FL72774LOGO)

CCS Medical is one of only 18 suppliers awarded CMS contracts to provide mail order diabetic testing supplies at competitively bid prices nationwide and in the four U.S. territories (American Samoa, Guam, Puerto Rico, and the U.S. Virgin Islands). As announced previously by CCS Medical, one of the brands that CCS Medical will be carrying is LifeScan's OneTouch® Ultra® test strips, the No. 1 brand recommended by endocrinologists and diabetes educators.

In addition, CCS Medical was awarded a CMS contract to provide Negative Pressure Wound Therapy (NPWT) pumps to beneficiaries in 87 of the 91 communities across the country that were competitively bid. The Competitive Bidding Program and the National Mail Order Program are scheduled to go into effect July 1, 2013.

"We are excited to be among this select group announced by CMS and to be servicing Medicare patients and reducing the cost of healthcare," said Dirk Allison, CCS Medical President and Chief Executive Officer. "We have been preparing for this development by improving our service and lowering our costs," he said. "We are ready to meet the needs of new patients and help them manage their chronic conditions by providing low-cost, high-quality products and services."

About CCS Medical
Established in 1994, CCS Medical is a rapidly growing provider of low-cost, high-quality products and services delivered directly to homes of patients with chronic conditions. The company offers a single source solution for diabetes testing supplies, insulin pumps, advanced wound care dressings, catheters, ostomy and incontinence supplies, and prescription medications. CCS Medical's patient-centered model specializes in convenient home delivery, product education, and insurance processing. CCS Medical is a privately held company and its largest shareholders are funds managed by Highland Capital Management, L.P. More information is available at www.ccsmed.com.

SOURCE CCS Medical

TRICARE Durable Medical Equipment Payment Appendix

Facility Name(s): DEGC Enterprises (US) Inc., Dba CCS Medical ("Provider")

Effective Date of this Appendix: 04/01/2013

APPLICABILITY

This Appendix applies to Covered Services rendered by the Provider to Beneficiaries covered under the TRICARE Program.

SECTION 1
Definitions

Unless otherwise defined in this Appendix, all capitalized terms used in this Appendix will have the meanings assigned to them in:

(1) the Agreement; and

(2) the TRICARE Program Requirements.

Customary Charge: The fee for health care services or supplies charged by the Provider that does not exceed the fee the Provider would ordinarily charge another person regardless of whether the person is a Beneficiary of the TRICARE Program.

TRICARE Maximum Rate: The maximum amount payable under the TRICARE Program, as described in the TRICARE Program Requirements, including without limitation 32 C.F.R. §199.14(j) (1) (i) and (ii), as amended from time to time, or any successor regulation. The TRICARE Maximum Rate is solely determined by the United States Department of Defense and its TRICARE Management Activity ("TMA") and is subject to change by the TMA at any time. To the extent that the TRICARE Maximum Rate is the CHAMPUS Maximum Allowable Charge (as defined in 32 C.F.R. §199.14(j)(1)(i)), it can be accessed at the following website link, which may be changed or updated from time to time: http://www.tricare.mil/CMAC/home.aspx.

SECTION 2
Reimbursement Rates for Covered Services

2.1 Reimbursement Rates for Durable Medical Equipment. For DME Codes with a TRICARE Maximum Rate, Reimbursement Rates for Covered Services will be the lesser of: (1) Provider's Customary Charge or (2) 70% of the TRICARE Maximum Rate.

In the event that the TRICARE Maximum Rate for a given Covered Service set forth in this Section 2.1 is not available, then the Reimbursement Rate for that Covered Service will be 50% of the Provider's Customary Charge Default Rate. All Reimbursement Rates are subject to applicable TRICARE Program Requirements including UMVS Policies.

2.2 **Code Updates.** UMVS will comply with the TRICARE Management Activity Change Order process to implement coding updates. When implementing coding updates, UMVS will apply the same percentage(s) as set forth above in Section 2.1 of this Appendix and the then current value of the published code to determine the contract rate.

2.3 **Other Payment Considerations.** Unless specifically indicated otherwise, any or all amounts are subject to reductions based on appropriate modifiers. Any Deductible or Cost Shares that the Beneficiary is responsible to pay will be subtracted from the Reimbursement Rate in determining the amount to be paid by UMVS. The actual payment amount is also subject to matters described in this Agreement or TRICARE Appendix with regard to TRICARE, such as the TRICARE Program Requirements including UMVS Policies.

SECTION 3
Adjustment to Contract Rates Due to Changes in Provider's Customary Charges

3.1 **Intent.** The intent of this Section is to allow Provider to modify its Customary Charges when and how Provider chooses, while assuring that increase to Provider's Customary Charges do not have a material impact of increasing the amount paid by Payers separately Cover Services under this Appendix.

3.2 **Request to Review Changes in Customary Charges.** Upon request, Provider will provide to UMVS a copy of their price list for all items that pay at the Default Rate on the day of the request and Provider will also provide a copy of the price list as of one year prior to the date of request. Provider will provide both files in a format proscribed by UMVS. Provider agrees that prices for items reimbursed at the Default Rate will not increase more than 5% within any 12 month period.

3.3 **Cooperation with UMVS.** Provider will cooperate with UMVS in administration of this section by timely meeting with UMVS to discuss and explain the information provided in accordance with Section 3.2, including Provider's calculation of the new Customary Charges.

3.4 **Adjustment to Contract Rates.** Upon receipt of the price lists described in Section 3.2, UMVS will adjust the default rate, using the estimates in the notice. UMVS will create and implement a new version of this Appendix. The revised appendix will be identical to this Appendix, other than the revised default rate will be set to assure the Default Rate does not exceed the intent of section 3.2 UMVS may implement the revised appendix without Provider's consent, provided that the revised appendix contains no other changes. UMVS will provide Provider with a copy of the revised Amendment, along with the effective date of the revised appendix.

3.5 **UMVS's right to audit.** In addition to any other audit rights that UMVS may have under the Agreement UMVS may conduct audits in connection with this Section 3. Provider will cooperate with the audit process and will provide to UMVS documentation that UMVS reasonably requests in order to perform such audits.

3.6 **Recovery of overpayments.** In the event that UMVS determines that an overpayment to Provider has resulted due to Provider's failure to fully disclose changes to Customary Charges affiliated codes reimbursed at the Default Rate, or due to the Provider providing inaccurate information, or due to Provider providing incorrect estimates of the adjustments needed to the contract rate UMVS may recover those overpayments. UMVS will give Provider notice of, and UMVS's intent to, recover the overpayment. The notice will identify UMVS's basis for believing

that an overpayment has occurred, how UMVS will recover the overpayment and how UMVS will prospectively adjust the contract rate to prevent additional overpayments from occurring. UMVS will timely meet with Provider, upon Provider's request, to discuss and explain the information in UMVS's notice, how UMVS calculated that information and why UMVS believes this information to be correct. In the event that Provider initiates dispute resolution as further described under Section 3.7, the recovery and adjustments described in this Section 3.6 will not take place until the conclusion of the dispute resolution process.

3.7 Dispute Resolution. In the event Provider disagrees with UMVS as to the existence of an overpayment or the amount of the overpayment, the issue will be resolved through the dispute resolution process set forth in the Agreement.

ANCILLARY FACILITY PARTICIPATION AGREEMENT FOR TRICARE PROGRAM

This Agreement is entered into by and between UnitedHealth Military & Veterans Services, LLC ("UMVS") and DEGC Enterprises (US) Inc., Dba CCS Medical ("Provider").

UMVS has entered into a contract with the United States Government to arrange for the provision of health and administrative services to beneficiaries of the TRICARE Program. UMVS desires to make Provider's services available to those beneficiaries. Provider wishes to provide those services, under the terms and conditions set forth in this Agreement.

This Agreement is effective on the latest of:

(i) April 1, 2013 or

(ii) the date the Department of Defense implements its TRICARE Contract with UMVS for health care delivery; or

(iii) the first day of the first month that begins at least 30 days after this Agreement has been executed by both parties; UMVS may implement an earlier effective date, and will give notice to Provider if it does so.

The parties therefore enter into this Agreement.

ARTICLE I. DEFINITIONS

The following terms when used in this Agreement have the meanings set forth below:

1.1 **Beneficiary.** A person who is eligible and enrolled (if required) to receive Covered Services under the TRICARE Program at the time services are rendered.

1.2 **Clean Claim.** A Clean Claim means a claim for payment for Contracted Services submitted by or on behalf of Provider which complies with all requirements set forth in the UMVS Policies, including the specific data elements required for a claim to be deemed a Clean Claim.

1.3 **Contracted Services.** Covered Services that are within Provider's scope of practice and provided to a Beneficiary pursuant to the TRICARE Program in effect at the time services are rendered and compensated in accordance with this Agreement.

1.4 **Continued Health Care Benefit Program.** A program that offers temporary transitional health coverage (18-36 months to individuals after their TRICARE eligibility ends).

1.5 **Coordination of Benefits.** The allocation of financial responsibility for Covered Services provided to a Beneficiary in accordance with the requirements specified in 32 C.F.R. 199 and the TRICARE Program Requirements.

1.6 **Cost Shares.** That portion of the cost of Covered Services that a Beneficiary is obligated to pay pursuant to the TRICARE Program Requirements (other than enrollment fees, Deductibles and disallowed amounts). Cost Shares may be structured as coinsurance, for which the Beneficiary's Cost Share is stated as a percentage of allowed charges, and copayments, for which the Beneficiary's Cost Share is stated as a fixed dollar amount.

1.7 **Covered Services.** The health care services and supplies that are covered under the TRICARE Program.

1.8 **Deductible.** The amount of allowable charges a Beneficiary must pay before the TRICARE Program pays certain benefits for Covered Services. Deductibles are not Cost Shares.

1.9 **Excluded Claim.** A claim retained while being developed for missing or discrepant information that cannot be obtained from UMVS's in-house sources; a third party liability claim requiring development; a claim requiring Government intervention, or a claim requiring interface with other contractors.

1.10 **Excluded Services.** Those health care services and supplies which are determined by UMVS not to be Covered Services under the TRICARE Program in effect at the time services are rendered and for which Provider may bill the Beneficiary.

1.11 **Medical Emergency.** A Medical Emergency shall have the meaning set forth in the TRICARE Program Requirements, including 32 C.F.R. 199.2, as the same may change from time to time.

1.12 **Medicare Eligible.** A Beneficiary age 65 or older or a disabled Beneficiary under age 65 who is eligible for care under the TRICARE Program and the Medicare entitlement program under Medicare Parts A and B.

1.13 **National Quality Monitoring Contractor (NQMC).** The NQMC is a national, external, independent, and impartial peer review contractor responsible for oversight of review related activities conducted under the TRICARE Program, including responsibility for provision of reconsideration, review of concurrent review denial determinations and appeal of reconsiderations of at-risk contractor review decisions.

1.14 **Network Provider.** A facility, physician, physician organization, other health care professional, supplier, or other entity engaged in the delivery of health care services which is licensed and/or certified as required under applicable law and which has been duly credentialed by UMVS or its designee and has, or is governed by, an effective written agreement directly with UMVS, or indirectly through another entity, such as another Network Provider, to provide Covered Services to Beneficiaries.

1.15 **Network Provider Handbook.** Manuals and handbooks provided by the TRICARE Program or UMVS for Network Providers in the UMVS TRICARE Program. The Network Provider Handbook will be updated from time-to-time through revisions, modifications or amendments, as well as through provider newsletters, bulletins or supplemental manuals or handbooks. The Network Provider Handbook will be available to Provider at www.unitedhealthcareonline.com or upon request.

1.16 **Primary Care Manager (PCM).** A Network Provider, or a clinic at a Military Treatment Facility (MTF), whose primary responsibility is to coordinate and manage the delivery of Covered Services to Beneficiaries selected or assigned to such Provider under TRICARE Prime.

1.17 **Prior Authorization.** The approval from UMVS required pursuant to the TRICARE Program Requirements prior to: (a) admitting a Beneficiary to a hospital, or (b) providing services on the Prior Authorization List, which can be found at www.unitedhealthcareonline.com.

1.18 **Referral.** The written request for services, with approval required pursuant to the TRICARE Program Requirements for a Beneficiary to receive Covered Services from a physician or other health care professional or organization.

1.19 **Reimbursement Rate.** The payment made to Provider for Covered Services provided to a Beneficiary as set forth in the Payment Appendix to this Agreement. The Reimbursement Rate is calculated in accordance with the TRICARE Program Requirements. In no event will the Reimbursement Rate exceed the maximum allowed by the TRICARE Program.

1.20 **Retained Claim.** A claim that contains sufficient information to allow processing to completion or for which any missing information may be developed from sources to which UMVS has direct access, including Defense Enrollment Eligibility Reporting System (DEERS) and UMVS files.

1.21 **State.** The state or states in which Provider is to provide Covered Services under this Agreement.

1.22 **TRICARE Prime.** An HMO-like option under the TRICARE Program, where Beneficiaries elect to enroll in a voluntary program which provides TRICARE benefits and enhanced primary and preventative benefits with nominal Beneficiary cost-sharing. TRICARE Prime generally requires Beneficiaries to use a PCM located at either a Military Treatment Facility or from a TRICARE contractor's network.

1.23 **TRICARE Prime Service Areas.** The entire area of all of the zip codes lying within or intersected by the forty (40) mile radius around each Military Treatment Facility (both hospitals and clinics) and Department of Defense Base Realignment and Closure (BRAC) sites, and all additional areas or sites designated by UMVS or the TRICARE Program Requirements.

1.24 **TRICARE Prime Remote.** TRICARE Prime Remote and TRICARE Prime Remote for Active Duty Family Members are parts of the TRICARE Program for Active Duty Service Members who are assigned to permanent duty stations not near sources of military medical care and their immediate family members.

1.25 **TRICARE Program.** A managed health care program operated by the United States Government through the authorized agency pursuant to Chapter 55 of Title 10 the United States Code and the regulations promulgated thereunder (32 C.F.R. 199).

1.26 **TRICARE Program Requirements.** All TRICARE Regulations and UMVS Policies and the terms and conditions of UMVS's TRICARE contract with the United States Government, as the same may change from time to time. A Freedom of Information Act (FOIA) releasable image of the TRICARE contract referenced in this section is available at www.unitedhealthcareonline.com.

1.27 **TRICARE Regulations.** All applicable TRICARE laws and regulations, operations manuals, system manuals, policy manuals and reimbursement manuals, including, but not limited to: Title 10, United States Code, Chapter 55; 32 C.F.R., Part 199; TRICARE Operations Manual (TOM); TRICARE Policy Manual (TPM); TRICARE Reimbursement Manual (TRM); and TRICARE Systems Manual (TSM), as the same may be amended from time to time. The TRICARE Manuals referenced in this section are available at www.unitedhealthcareonline.com.

1.28 **TRICARE Reserve Select.** TRICARE Reserve Select is a part of the TRICARE Program that offers TRICARE Standard and Extra health coverage to qualified members of the Selected Reserve and National Guard and their immediate family members.

1.29 **UnitedHealthcare Online®.** The website that currently serves as a resource to providers to access certain UMVS information relating to the TRICARE Program is www.unitedhealthcareonline.com. If the website changes in the future, UMVS will notify Provider.

1.30 **Utilization Management Plan.** UMVS's Utilization Management Plan, and the TRICARE Program Requirements relating thereto. The UMVS Utilization Management Plan is part of the UMVS Policies and will be available to Provider at www.unitedhealthcareonline.com.

1.31 **UMVS Policies.** The policies, procedures and programs established by UMVS and applicable to Network Providers in effect at the time services are rendered to a Beneficiary, including, without limitation, the Network Provider Handbook, credentialing and quality management and improvement programs, fraud detection and recovery procedures, eligibility verification, payment and coding guidelines, anti-discrimination requirements, utilization management, case management and disease management plans and programs, grievance and appeal procedures, provider dispute and/or administrative review process. The UMVS Policies are documented and may be modified from time-to-time through revisions, supplements, modifications or amendments, as well as through provider newsletters, bulletins or supplemental releases. The UMVS Policies will be available to Provider at www.unitedhealthcareonline.com.

ARTICLE II. PROVIDER REPRESENTATIONS AND WARRANTIES

Provider represents and warrants that it is and shall at all times during the term of this Agreement continue to:

(a) be licensed or otherwise authorized, without restriction or limitation, by the State(s) to provide Contracted Services;
(b) operate and provide Contracted Services in compliance with the TRICARE Program Requirements and all applicable local, State, and Federal laws, rules, regulations and professional standards of care;
(c) be a TRICARE-authorized and certified provider pursuant to 32 C.F.R. 199.6;
(d) be certified to participate in Medicare under Title XVIII of the Social Security Act, for those classes of providers recognized by Medicare;
(e) must be a participating provider for all claims, per 32 CFR 199.6 a(8)(i).
(f) maintain accreditation by The Joint Commission, or meet UMVS Credentialing requirements;
(g) maintain a current DEA narcotic registration certificate, where applicable, and current State narcotics license, where applicable.

Moreover, Provider represents that it:

(h) is not and has not been suspended, excluded, barred or sanctioned by Medicare, Medicaid, or any other State or Federal program or agency (or notified of such action);
(i) is not and has not been convicted of or indicted for any criminal offense related to healthcare (unless the indictment was dismissed without conviction); and has not been otherwise engaged in conduct for which a person or entity can be so convicted, indicted or listed.

ARTICLE III PROVIDER OBLIGATIONS

3.1 **Provision of Services.** Provider will render Contracted Services to Beneficiaries, in accordance with the terms and conditions of this Agreement, including all TRICARE Program Requirements. Provider shall be solely responsible for the quality of Contracted Services rendered by Provider to Beneficiaries. In the event that Provider is uncertain as to whether a service is a Contracted Service, Provider shall contact UMVS to obtain a coverage determination prior to rendering services, except in a Medical Emergency.

3.2 **UMVS Policies and Provider Education.** Provider will participate in, cooperate with and comply with all UMVS Policies. Provider shall participate in TRICARE education efforts, and shall require all staff members to participate in TRICARE education efforts described in the Network Provider Handbook so that Provider and Provider's staff members understand applicable TRICARE Program Requirements to enable them to carry out the requirements of this Agreement in an efficient and effective manner which promotes Beneficiary satisfaction.

3.3 **Credentialing of Provider.** Provider shall submit to UMVS or its designee a credentials application which meets the requirements of UMVS, to the extent it is subject to credentialing. The credentials application must be approved by UMVS or its designee prior to any performance taking place under this Agreement.

3.4 **Hours of Operation/Access.** At a minimum, Provider will be open during normal business hours, Monday through Friday. If the Provider provides emergency services, such as ambulance services, Provider will be open 24 hours per day, seven days a week.

3.5 **Eligibility.** Except in a Medical Emergency, Provider shall verify the eligibility of Beneficiaries before providing Contracted Services. UMVS shall make a good faith effort to confirm the eligibility of any Beneficiary upon request. Eligibility of all Beneficiaries must be verified by the designated agent of such program (e.g. Defense Enrollment Eligibility Reporting System). However if the designated agent initially indicates that a patient is a Beneficiary and that patient is later determined to have been ineligible at the time of service, then UMVS may deny any claims for payment due to non-eligibility and Provider may seek compensation from the patient or other responsible party. If Provider exercised reasonable care to determine eligibility and to seek payment from the patient or other responsible party but has been unable to obtain compensation the Provider may submit the claim to UMVS for a good faith payment, subject to government approval in accordance with TRICARE procedures.

3.6 **Notice of Adverse Action.** Provider shall notify UMVS within five (5) days of the occurrence of any of the following:

(a) Any action taken to restrict, suspend or revoke Provider's license or authorization to provide Contracted Services;
(b) Any suit or arbitration action brought by a patient against Provider for malpractice. In addition, Provider shall send UMVS a summary of the final disposition of such action;
(c) Any misdemeanor conviction or felony information or indictment naming Provider. In addition, Provider shall send UMVS a summary of the final disposition thereof;
(d) Any disciplinary proceeding or action naming Provider before an administrative agency in any state. In addition, Provider shall send UMVS a summary of the final disposition thereof;
(e) Any cancellation or material modification of the professional liability insurance required to be carried by Provider under the terms of this Agreement;

(f) Any action taken to restrict, suspend or revoke Provider's participation in Medicare, Medicaid or CHAMPUS, TRICARE or any succeeding program. In addition, Provider shall send UMVS a summary of the final disposition thereof;
(g) Any action which results in the filing of a report on Provider under applicable laws and/or regulations relating to the provision of, or the billing and payment for, Covered Services. In addition, Provider shall send UMVS a summary of the final disposition thereof;
(h) Any material Beneficiary complaints against Provider; or
(i) Any other event or situation that could materially affect Provider's ability to carry out Provider's duties and obligations under this Agreement.

3.7 **Non-Discrimination.** Provider shall not discriminate against any Beneficiary in the provision of Contracted Services hereunder, whether on the basis of the Beneficiary's coverage under the TRICARE Program, age, sex, marital status, sexual orientation, race, color, religion, ancestry, national origin, disability, handicap, health status, source of payment, utilization of medical or mental health services, equipment, pharmaceuticals or supplies, or other unlawful basis including, without limitation, the filing by such Beneficiary of any complaint, grievance or legal action against Provider or UMVS. Provider will make reasonable accommodations for Beneficiaries with disabilities or handicaps, in accordance with all applicable law, including but not limited to, providing such auxiliary aides and services to Beneficiaries at the Provider's expense as are reasonable, necessary and appropriate for the proper rendering of Contracted Services.

3.8 **Subcontracting.** Provider shall not subcontract for the performance of Covered Services under this Agreement without the prior written consent of UMVS. Every subcontract between Provider and a subcontractor must comply with all applicable laws, be consistent with the terms and conditions of this Agreement, and be terminable with respect to Beneficiaries upon request of UMVS.

3.9 **Utilization Management Plan.** Provider will comply with all provisions of the Utilization Management Plan, including the provision of medical records and other documentation. Provider further authorizes UMVS to release all review data obtained through medical record and other document audits to National Quality Monitoring Contractors selected by the TRICARE Management Activity.

3.10 **Prior Authorization.** When Prior Authorization is required pursuant to the TRICARE Program Requirements, the receipt of required Prior Authorization is a prerequisite to payment of the claim for services. Payment shall be reduced in accordance with the TRICARE Program Requirements, for any service subject to Prior Authorization that was not obtained and the Provider may not bill the Beneficiary. Prior Authorization is not a guarantee of payment; payment determinations are made after the claim is submitted for payment, based on a variety of factors, including the eligibility of the patient and whether the service is a Covered Service. UMVS will not retroactively deny reimbursement for a Contracted Service provided to a Beneficiary who relied on UMVS's Prior Authorization, provided that there was no misrepresentation or fraud in the request for Prior Authorization. In a Medical Emergency, Provider shall notify UMVS and the appropriate PCM as applicable, as soon as possible but no later than twenty-four (24) hours after providing Contracted Services that would otherwise require Prior Authorization. Subject to administrative review, UMVS shall have the final binding authority to make decisions regarding whether a given situation constituted a Medical Emergency for purposes of determining Covered Services consistent with TRICARE Program Requirements. If UMVS determines that a Medical Emergency did not exist, payment shall be reduced in

accordance with the TRICARE Program Requirements, and the Provider may not bill Beneficiary directly.

3.11 **Referrals.** When required by the TRICARE Program Requirements, the Military Treatment Facility ("MTF") has the right of first refusal for all Referrals, and the MTF must have the opportunity to review each Referral from a civilian provider to determine if the MTF has the capability and capacity to provide the treatment. Beneficiaries gain access to the civilian TRICARE provider network only through Referral or Prior Authorization. Provider will provide services to Beneficiaries for non-Medical Emergency services only after obtaining the requisite Referral and/or Prior Authorization, where applicable, in accordance with the TRICARE Program Requirements. Provider shall not refer Beneficiaries to Providers in which Provider has an economic interest, as defined in the TRICARE Regulations.

3.12 **Network Providers.** Except in a Medical Emergency, as otherwise described in the applicable TRICARE Program Requirements, or as otherwise required by law, Provider shall refer Beneficiary only to Network Providers for Covered Services. For certain specialized procedures and services which cannot be rendered by the Network Providers, UMVS may require that the most cost effective, qualified Provider be utilized for such care. In the event Provider refers a Beneficiary to a non-Network Provider without a Referral or without Prior Authorization when either or both are required by the TRICARE Program Requirements, Provider will be responsible for payment of claims incurred for the unauthorized service, and Provider will hold harmless the Beneficiary for such claims. Provider shall use reasonable commercial efforts to assist UMVS in its efforts to contract with Provider's Facility-based physicians.

3.13 **Quality Management and Improvement Program.** The quality of Covered Services rendered by Provider to Beneficiaries is subject to the quality management and improvement program described in the UMVS Policies. Provider will participate in, cooperate with and comply with all quality management and improvement program requirements and all decisions rendered by UMVS in connection with the quality management and improvement program. Provider also will provide, within ten (10) days of receipt of written notice, all medical records, review data and other information as may be required or requested under the quality management and improvement program per the payment requirements set forth in Section 7.2.

3.14 **Liability Insurance.** Provider will procure and maintain liability insurance. Except to the extent coverage is a state mandated placement, Provider's coverage must be placed with responsible, financially sound insurance carriers authorized or approved to write coverage in the state in which the Covered Services are provided. Provider's liability insurance must be, at a minimum, of the types and in the amounts set forth in the attached Liability Insurance Requirements Table. Provider's medical malpractice insurance must be either occurrence or claims made with an extended period reporting option. Prior to the Effective Date of this Agreement and within ten (10) days of each policy renewal thereafter, Provider will submit to UMVS in writing evidence of insurance coverage.

3.15 **Listing of Provider.** UMVS and its designees may list the name, address, telephone number and other factual information of Provider, in its marketing and informational materials. In no event shall Provider market/advertise the TRICARE Program without the prior written consent of UMVS, except that Provider may make known the fact that it is a participating provider with UMVS for the TRICARE Program.

3.16 **Identification Number/Payment of Taxes**. Provider shall notify UMVS in writing, thirty (30) days in advance, of any changes to Provider's federal tax identification numbers or national provider identification numbers. Provider shall compensate UMVS for any fine associated with incorrect federal tax identification numbers or national provider identification numbers, should Provider fail to timely notify UMVS in writing. Provider is solely responsible for the collection and payment of any sales, use or other applicable taxes on the sale or delivery of medical services.

3.17 **Provider's Services.** This Agreement applies to Provider's practice locations at the time of the Effective Date. In the event Provider begins providing services at other locations (either by opening such locations itself, or by acquiring, merging or coming under common ownership and control with an existing provider of services that was not already under contract with UMVS to provide Covered Services to TRICARE Beneficiaries), such additional locations will become subject to this Agreement thirty (30) days after UMVS receives the notice required under Section 3.16 of this Agreement.

In the event Provider acquires or is acquired by, merges with, or otherwise becomes affiliated with another provider of health care services that is already under contract with UMVS to provide Covered Services to TRICARE Beneficiaries, this Agreement and the other agreement will each remain in effect and will continue to apply as they did prior to the acquisition, merger or affiliation, unless otherwise agreed to in writing by all parties to such agreements.

Provider may transfer all or some of its assets to another entity, if the result of such transfer would be that all or some of the Covered Services subject to this Agreement will be rendered by the other entity rather than by Provider, but only if Provider requests that UMVS approve the assignment of this Agreement as it relates to those Covered Services and only if the other entity agrees to assume this Agreement. This paragraph does not limit UMVS's right under Section 8.4 of this Agreement to elect whether to approve the assignment of this Agreement.

ARTICLE IV. OTHER FEDERAL GOVERNMENT PROGRAMS

4.1 **Veterans Affairs Patients.** Provider agrees that UMVS may report Provider to the Department of Veterans Affairs ("VA") as a TRICARE Network Provider. Provider is requested to accept requests from the VA to provide care to veterans and shall notify UMVS on a monthly basis of such acceptances. The VA has the right to directly contact Provider and request the provision of care to veteran patients on a case by case basis. Provider is not obligated to see the veteran patient, but, if seen by Provider, any documentation of the care rendered to the veteran patient and reimbursement for the care is a matter between the referring VA Medical Center ("VAMC") and Provider. The Referral and instructions for seeking reimbursement from the VAMC will be provided by the veteran patient to Provider at the time of the appointment. The VA and Provider may establish a direct contract relationship if they so desire.

4.2 **Responsibilities to Civilian Health and Medical Program of the Department of Veterans Affairs.** Provider will permit UMVS to report Provider to the Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA") as a TRICARE Network Provider. Provider is requested to accept assignment for CHAMPVA beneficiaries and shall notify UMVS on a monthly basis of such acceptances. Provider need see CHAMPVA beneficiaries only when Provider's practice availability allows and shall not give preferential appointment scheduling to CHAMPVA over TRICARE appointments. Provider is encouraged to meet access standards for CHAMPVA beneficiaries. UMVS will provide Provider with

CHAMPVA claims processing instructions on submitting CHAMPVA claims to the VA Health Administration Center for payment. Provider may, at Provider's discretion, offer the negotiated TRICARE discount directly to CHAMPVA.

4.3 **National Disaster Medical System (NDMS).** Provider is encouraged to become a member of NDMS.

ARTICLE V SUBMISSION, PROCESSING AND PAYMENT OF CLAIMS

5.1 **Submission of Claims.** Provider shall submit all claims electronically to UMVS. All paper claims submitted by Provider will be returned to Provider with directions to submit electronically. Provider shall specify Provider's elected means of claim submission on the Provider Demographic Form sent with this Agreement. Provider may change Provider's selection of means for submitting claims pursuant to this Agreement upon sixty (60) days advance written notice to UMVS. Claims shall be submitted as complete, accurate Clean Claims in a format approved by UMVS for Contracted Services rendered to Beneficiaries.

Claims must be submitted within three hundred sixty five (365) days after the date of service or discharge, except that where UMVS is the secondary payer under Coordination of Benefits, this timely filing period will commence once the primary payer has made payment on or has denied the claim, as evidenced by the date on the Explanation of Benefits (EOB) statement. Any such claim to UMVS as a secondary payer is also subject to the requirement that it be submitted to UMVS within twelve (12) months after the date of service or discharge. Claims received by UMVS beyond the timely filing periods specified in this Section 5.1 may be denied. Provider shall not seek or accept payment from the Beneficiary in the event UMVS does not pay Provider for a claim not submitted in a timely manner. Additionally, electronic claims must comply with standardized electronic transactions and code sets as required pursuant to the Health Insurance Portability and Accountability Act ("HIPAA").

Provider will comply with TRICARE Program Requirements when billing and collecting and/or seeking administrative review of payment for Contracted Services rendered pursuant to this Agreement. UMVS may determine the accuracy and appropriateness of all claims submitted to it, including but not limited to verification of diagnostic codes, DRG assignment, procedure codes and other elements of the submitted claim that affect the liability of UMVS. Based on its review of the accuracy and appropriateness of claim information submitted by Provider, UMVS may modify such information and use the modified information as the basis for payment of Contracted Services. UMVS shall include with its payment an explanation of the reasons for any modification of submitted information.

5.2 **Reimbursement.** UMVS, on behalf of the United States Government, will pay claims for Covered/Contracted Services as further described in the applicable Payment Appendix to this Agreement, and in accordance with UMVS Policies and the TRICARE Program Requirements. The Reimbursement Rates will be reduced by the amount of the Cost Shares and Deductibles to determine the amount to be paid by UMVS. Provider will accept the Reimbursement Rates, including any applicable Cost Shares or Deductibles, as payment in full for Covered Services. In no event will reimbursement for Covered Services exceed the maximum allowed by the TRICARE Program.

5.3 **Active Duty Personnel.** Provider shall render Covered Services to United States military active duty personnel and seek compensation for the Supplemental Health Care Program (SHCP) and

TRICARE Prime Remote (TPR) Program from UMVS at the Reimbursement Rates, and in accordance with the requirements of those programs, and as set forth in this Agreement and the TRICARE Program Requirements.

5.4 **Collection of Cost Shares and Deductible.** Provider shall collect applicable Cost Shares and Deductibles from the Beneficiary. Provider shall not require payment from a Beneficiary for any Excluded Service except in accordance with Section 5.7 of this Agreement.

5.5 **No Surcharges.** Provider shall not charge the Beneficiary any fees or surcharges other than applicable Cost Shares and Deductibles for Covered Services rendered pursuant to this Agreement or any membership fee or other fee as a prerequisite for accepting a Beneficiary as a patient. In addition, Provider shall not collect sales, use or other applicable tax from Beneficiaries for the sale or delivery of medical services. If UMVS receives notice of any additional charge, Provider shall fully cooperate with UMVS to investigate such allegations, and shall promptly refund any payment deemed improper by UMVS to the party who made the payment.

5.6 **Beneficiary Hold Harmless.** Provider acknowledges that Beneficiaries do not have financial responsibility for any Covered Services, except applicable Cost Shares and/or Deductibles. Provider agrees that in no event, including, but not limited to, non-payment by UMVS, the insolvency of UMVS, or breach of this Agreement, shall Provider bill, charge, collect a deposit from, seek compensation, remuneration, or reimbursement from, or have any recourse against Beneficiaries or persons other than UMVS for Covered Services. This provision shall not prohibit collection of Cost Shares and/or Deductibles on UMVS's behalf made in accordance with the terms of the applicable TRICARE Program. This provision shall survive termination of this Agreement, regardless of the cause giving rise to termination. This provision supersedes any oral or written contrary agreement now existing or hereafter entered into between Provider and Beneficiaries or persons acting on their behalf.

5.6.1 **Charges.** Provider shall not charge Beneficiaries for the following services: services for which Provider is entitled to payment from TRICARE (other than any applicable Cost-Shares/Deductibles); services for which the Beneficiary would be entitled to have TRICARE payment made had Provider complied with TRICARE Program Requirements and UMVS Policies; services not medically necessary and appropriate for the clinical management of the presenting illness, injury, disorder or maternity; services for which a Beneficiary would be entitled to have TRICARE payment made but for a reduction or denial in payment as a result of quality review; and services rendered during a period in which Provider was not in compliance with one or more conditions of authorization pursuant to the TRICARE Program Requirements and UMVS Policies.

5.7 **Conditions for Reimbursement for Excluded Services.** Neither a Beneficiary nor UMVS shall be liable to pay Provider for any Excluded Service, except that Provider may bill a Beneficiary for Excluded Services rendered by Provider to such Beneficiary if the Beneficiary is notified in advance that the services to be provided are not a Covered Medical Service under the Beneficiary's TRICARE Program, and the Beneficiary requests in writing that Provider render the Excluded Services, prior to Provider's rendition of such services. All such waivers must be specific as to the details and cost of the Excluded Services to be provided. General forms which are signed by a Beneficiary prior to the office visit or admission or which lack specific details and costs of the services to be provided are not adequate.

5.8 **Coordination of Benefits.** Provider shall adhere to the Coordination of Benefits policies and procedures set forth in the UMVS Policies and other TRICARE Program Requirements, including, without limitation, the obligation to provide prompt notification to UMVS of any third party who may be responsible for payment. Provider will maintain and make available to UMVS records reflecting collection of Coordination of Benefits proceeds by Provider and, when available to Provider, records reflecting amounts paid to Beneficiary. Provider shall not bill Beneficiaries for any portion of Covered Services not paid by the primary carrier when TRICARE is the secondary carrier, but shall instead look to UMVS for secondary payment. When a Beneficiary has coverage which is primary through another carrier, UMVS's payment to Provider shall be limited to the difference between the amount paid by the primary payer and the Reimbursement Rates, including Cost Shares and/or Deductibles. When a Beneficiary has coverage which is primary through another carrier, then UMVS compensation to provider shall be secondary.

5.9 **Third Party Recoveries.** If UMVS has compensated Provider for Covered Services, UMVS retains the right to recover from applicable third parties responsible for payment for services rendered to a Beneficiary and to retain all such recoveries. Provider will provide UMVS with such information as UMVS may require in order to pursue recoveries from such third party sources, and to promptly remit to UMVS any monies Provider may receive from or with respect to such sources of recovery.

5.10 **Recoupments.** UMVS may recover from Provider at any time amounts owed to UMVS pursuant to TRICARE Program Requirements, including payments that were made beyond or outside what is provided for under this Agreement. Subject to the TRICARE Program Requirements, UMVS shall have the right to offset overpayments and other amounts Provider owes UMVS against future payments otherwise due to Provider.

5.11 **TRICARE for Medicare Eligibles.** Provider will render Covered Services to Medicare-eligible Beneficiaries of the TRICARE Program in accordance with the terms and conditions of the TRICARE Program and all applicable Medicare laws, regulations and Centers for Medicare & Medicaid Services (CMS) instructions. Provider will accept assignment for services provided under Medicare and to submit claims on behalf of all TRICARE and Medicare beneficiaries.

5.12 **TRICARE Contract Phase-Out.** Provider will use reasonable commercial efforts to submit all TRICARE claims within thirty (30) days from date of service or discharge during the phase-out period of UMVS's TRICARE contract with the United States Government. UMVS will notify Provider of the phase-out.

ARTICLE VI TERM AND TERMINATION

6.1 **Term.** This Agreement shall take effect on the Effective Date. This Agreement shall have an initial term of five years and renew automatically for renewal terms of one year, until terminated pursuant to this ARTICLE VI.

6.2 **Immediate Termination.** UMVS may terminate this Agreement immediately upon notice to Provider, in the event of: (a) Provider's violation of any applicable law, rule or regulation; (b) Provider's failure to maintain the liability insurance coverage required under this Agreement; (c) any situation involving an investigation conducted or complaint filed by a state or federal agency or licensing board that restricts Provider's ability to practice medicine; results in limitation of or discipline against, Provider's license, accreditation, or certification; (d) UMVS's determination

that the health, safety or welfare of any Beneficiary may be in jeopardy if this Agreement is not terminated; (e) any indictment, charge, arrest or conviction of a felony, or any criminal charge related to the medical, financial and other practices of Provider; (f) Provider's failure to meet UMVS's credentialing criteria or comply with UMVS's credentialing policies, (g) Provider's failure to maintain compliance with any of the Representations and Warranties set forth in this Agreement, or (h) the loss, suspension or restriction of Provider's license to practice medicine, narcotic registration certificate issued by the Drug Enforcement Administration, certification or authorization to participate in Medicare or Medicaid, CHAMPUS or TRICARE, or loss of medical staff privileges.

6.3 **Termination Due to Material Breach.** In the event that either Provider or UMVS fails to cure a material breach of this Agreement within sixty (60) days of receipt of written notice to cure from the other, the non-defaulting party may terminate this Agreement, effective as of the expiration of said sixty (60) day period. If the breach is cured within such sixty (60) day period, this Agreement shall remain in full force and effect.

6.4 **Voluntary Termination.** This Agreement may be terminated by mutual written agreement of the parties or by either party, upon at least one hundred eighty (180) days prior written notice, effective at the end of the initial term or effective at the end of any renewal term. Such written notice must specifically reference termination of this Agreement to provide services to Beneficiaries of the TRICARE Program in order to be deemed valid notification of Voluntary Termination.

6.5 **Continuation of Services After Termination.** In the event that Beneficiary is receiving Covered Services at the time this Agreement terminates, Provider shall continue to provide Covered Services to the Beneficiary until: (a) treatment is completed or ninety (90) days following termination, whichever first occurs; or (b) the Beneficiary is assigned to another Network Provider; or (c) Beneficiary ceases to be covered. Compensation for such Covered Services shall be at the Reimbursement Rates.

6.6 **Beneficiary Notification.** Provider shall notify any Beneficiary seeking services after the date of termination that the Provider is no longer a Network Provider. The parties agree to cooperate in good faith and without disparagement in connection with information supplied to Beneficiaries in connection with any termination or non-renewal of this Agreement.

ARTICLE VII. RECORDS, AUDITS AND REGULATORY REQUIREMENTS

7.1 **Medical and Other Records.** Provider will prepare, maintain and make available all medical and other records pursuant to the TRICARE Program Requirements and applicable law. Provider shall maintain such records for at least seven (7) years after the rendering of Covered Services (records of a minor child shall be kept for at least one (1) year after the minor has reached the age of eighteen (18), but in no event less than seven (7) years). Additionally, Provider shall prepare, maintain and make available such financial, administrative and other records as may be necessary for compliance by UMVS with all applicable laws for said seven (7) years.

7.2 **Access to Records; Audits.** Subject to applicable confidentiality or privacy laws, Provider shall permit UMVS and its designated representatives, and designated representatives of regulatory agencies having jurisdiction over UMVS or Provider (the "Authorized Parties"), access to Provider's records, at Provider's place of business during normal business hours, in order to inspect and review and make copies of such records. When requested by an Authorized Party,

Provider shall produce copies of any such records at no charge. Additionally, Provider will permit the Authorized Parties, to conduct audits, site evaluations and inspections of Provider's offices, service locations and records at no cost to the Authorized Parties within a reasonable time period, but not more than five (5) days after the request is submitted to Provider.

7.3 **HIPAA Compliance**. The parties will safeguard Beneficiary privacy and confidentiality as required by applicable law, including, without limitation, the United States Department of Health and Human Services Standards for Privacy of Individually Identifiable Health Information promulgated pursuant to the administrative simplification provisions of the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

7.4 **Provision of Records to Beneficiary**. Provider will furnish each Beneficiary with a copy of his/her medical record at no charge (to include a narrative summary and other documentation of care) within two (2) business days of the request.

7.5 **Behavioral Health Records**. If Provider offers behavioral health services and the Beneficiary authorizes release of the information, Provider shall submit to the Beneficiary's Primary Care Manager a copy of the record of the treatment provided.

7.6 **Continuing Obligation**. The obligations of Provider under this ARTICLE VII shall survive termination of this Agreement. After termination of this Agreement, UMVS shall continue to have access to Provider's records as necessary to fulfill the requirements of this Agreement and to comply with all applicable laws, rules and regulations.

ARTICLE VIII. MISCELLANEOUS PROVISIONS

8.1 **Entire Agreement**. This Agreement is the entire agreement between the parties with regard to the subject matter herein, and supersedes any prior written or unwritten agreements between the parties or their affiliates with regard to the same subject matter. This Agreement does not supersede any existing agreements between the parties or their affiliates with regard to benefit plans other than those addressed in this agreement, or prevent the parties or their affiliates from entering into such amendments or agreements in the future.

8.2 **Amendment**. This Agreement may only be amended through written or electronic notice by UMVS. That notice must be given at least ninety (90) days in advance of the effective date of the amendment, except that at least thirty (30) days advance notice is required for amendments made in order to comply with TRICARE Program Requirements or accreditation requirements (unless a shorter notice is necessary in order to accomplish compliance). Provider's signature is not required to make the amendment effective.

If the amendment is not required by TRICARE Program Requirements or is not an accreditation requirement, and the Provider believes that the amendment includes a material adverse change to the Agreement, the Provider may terminate this Agreement on sixty (60) days written notice to UMVS as long as the Provider sends this termination notice within thirty (30) days of Provider's receipt of the amendment.

8.3 **Nonwaiver**. The waiver by either party of any breach of any provision of this Agreement shall not operate as a waiver of any subsequent breach of the same or any other provision.

8.4 **Assignment.** This Agreement may not be assigned by either party without the written consent of the other party, except that this Agreement may be assigned by UMVS to any of UMVS's affiliates or to any other entity that enters into a contract with the United States Government for the TRICARE Program without the consent of Provider. Neither this Agreement, nor any of Provider's rights or obligations hereunder, is assignable by Provider without the prior written consent of UMVS.

8.5 **Relationship of the Parties.** The sole relationship between the parties to this Agreement is that of independent contractors. This Agreement does not create a joint venture, partnership, agency, employment or other relationship between the parties.

8.6 **No Third-Party Beneficiaries.** Except as expressly stated herein, UMVS and Provider are the only entities with rights and remedies under the Agreement.

8.7 **Delegation.** UMVS may delegate (but not assign) certain of its administrative duties under this Agreement to one or more other entities. No such delegation will relieve UMVS of its obligations under this Agreement.

8.8 **Notice.** Any notice required to be given under this Agreement shall be in writing, except in cases in which this Agreement specifically permits electronic notice, or as otherwise permitted or required in the TRICARE Program Requirements. All written or electronic notices shall be deemed to have been given when delivered in person, by electronic communication, by facsimile or, if delivered by first-class United States mail, on the date mailed, proper postage prepaid and properly addressed to the appropriate party at the address set forth on the signature portion of this Agreement or to another more recent address of which the sending party has received written notice. Notwithstanding the previous sentence, all notices of termination of this Agreement by either party must be sent by certified mail, return receipt requested. Each party shall provide the other with proper addresses, facsimile numbers and electronic mail addresses of all designees that should receive certain notices or communication instead of that party.

8.9 **Confidentiality.** Neither party will disclose to a Beneficiary, other health care providers, or other third parties any of the following information (except as required by an agency of the Government):

a) any proprietary business information, not available to the general public, obtained by the party from the other party; or
b) the specific reimbursement amounts provided for under this Agreement, except for purposes of administration of benefits.

At least forty eight (48) hours before either party issues a press release, advertisement, or other media statement about the business relationship between the parties, that party will give the other party a copy of the material the party intends to issue.

8.10 **Governing Law.** This Agreement will be governed by and construed in accordance with TRICARE Program Requirements and the laws of the state(s) in which Provider renders Contracted Services (except where preempted by Federal law), and any other applicable law. Any provision required to be in this Agreement pursuant to the TRICARE Program Requirements shall bind Provider and UMVS, whether or not set forth herein. Any provision required to be in this Agreement pursuant to TRICARE Regulations or other applicable laws shall bind the parties,

whether or not expressly set forth herein. The parties agree to comply with all applicable laws, rules and regulations regarding the performance of their obligations under this Agreement.

8.11 **Notification of Certain Employment Decisions.** Provider shall provide prompt written notification to UMVS of Provider's employment of an individual who, at any time during the twelve months preceding such employment, was employed in a managerial, accounting, auditing, or similar capacity by an agency or organization which is responsible, directly or indirectly, for decisions regarding Department of Defense payments to Provider.

8.12 **Severability.** Any provision of this Agreement that is unlawful, invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining provisions of this Agreement or the lawfulness, validity or enforceability of the offending provision in any other situation or jurisdiction.

8.13 **Indemnification of the United States.** Provider will indemnify, defend and hold harmless the United States Government from any and all claims, judgments, costs, liabilities, damages and expenses, including attorneys' fees, arising from any acts or omissions of Provider.

8.14 **Dispute Resolution.** Provider and UMVS (each a "Party" and collectively "Parties" to this Agreement) will work together in good faith to resolve any and all disputes between them (hereinafter referred to as "Disputes") including but not limited to all questions of arbitrability, the existence, validity, scope or termination of this Agreement or any term thereof.

If the Parties are unable to resolve any such Dispute within sixty (60) days following the date one Party sent written notice of the Dispute to the other Party, and if either Party wishes to pursue the Dispute, it shall thereafter be submitted to binding arbitration in accordance with the Commercial Dispute Procedures of the American Arbitration Association, as they may be amended from time to time (see http://www.adr.org). Unless otherwise agreed to in writing by the Parties, the Party wishing to pursue the Dispute must initiate the arbitration within one year after the date on which notice of the Dispute was given or shall be deemed to have waived its right to pursue the dispute in any forum.

Any arbitration proceeding under this Agreement shall be conducted in Dallas County, TX. The arbitrator(s) may construe or interpret but shall not vary or ignore the terms of this Agreement and shall be bound by controlling law. The arbitrator(s) shall have no authority to award punitive, exemplary, indirect or special damages, except in connection with a statutory claim that explicitly provides for such relief.

The Parties expressly intend that any dispute relating to the business relationship between them be resolved on an individual basis so that no other dispute with any third party(ies) may be consolidated or joined with our dispute. The Parties agree that any arbitration ruling by an arbitrator allowing class action arbitration or requiring consolidated arbitration involving any third party(ies) would be contrary to their intent and would require immediate judicial review of such ruling.

If the Dispute pertains to a matter which is generally administered by certain UMVS procedures, such as a credentialing or quality improvement plan, the policies and procedures set forth in that plan must be fully exhausted by Provider before Provider may invoke any right to arbitration under this Section 8.14.

The decision of the arbitrator(s) on the points in dispute will be binding, and judgment on the award may be entered in any court having jurisdiction thereof. The Parties acknowledge that because this Agreement affects interstate commerce the Federal Arbitration Act applies.

In the event that any portion of this Section 8.14 or any part of this Agreement is deemed to be unlawful, invalid or unenforceable, such unlawfulness, invalidity or unenforceability shall not serve to invalidate any other part of this Section 8.14 or this Agreement. In the event any court determines that this arbitration procedure is not binding or otherwise allows litigation involving a Dispute to proceed, the Parties hereby waive any and all right to trial by jury in, or with respect to, such litigation. Such litigation would instead proceed with a judge as the finder of fact.

In the event a Party wishes to terminate this Agreement based on an assertion of uncured material breach, and the other Party disputes whether grounds for such a termination exist, the matter will be resolved through arbitration under this Section 8.14. While such arbitration remains pending, the termination for breach will not take effect.

This Section 8.14 governs any dispute between the Parties arising before or after execution of this Agreement and shall survive any termination of this Agreement.

8.15 **Survival**. The following sections shall survive termination of this Agreement:

3.13 Quality Management and Improvement Program.
3.14 Liability Insurance (for obligation to maintain tail coverage)
5.2 Reimbursement
5.5 No Surcharges
5.6 Beneficiary Hold Harmless and 5.6.1 Charges
5.7 Conditions for Reimbursement for Excluded Services
5.8 Coordination of Benefits
5.9 Third Party Recoveries
5.10 Recoupments
6.5 Continuation of Services After Termination
6.6 Beneficiary Notification
ARTICLE VII - Records, Audits & Regulatory Requirements
8.9 Confidentiality
8.10 Governing Law
8.13 Indemnification of the United States
8.14 Dispute Resolution

{Signatures to follow}

IN WITNESS WHEREOF, the parties have executed this Agreement to be effective on the Effective Date.

Provider DEGC Enterprises (US) Inc., Dba CCS Medical	Address to be used for giving notice to Provider under this Agreement:
Signature W. Bradley Bickham	Street 1505 LBJ Freeway, Suite 600
Print Name W. Bradley Bickham	City Farmers Branch
Title EVP/CLO	State TX Zip Code 75234
Date 3/21/2013	Email ccs.contracts@ccsmed.com
Federal Tax Identification Number	593271823
Name of Tax Identification Owner	DEGC Enterprises (U.S.), Inc.

UnitedHealth Military & Veterans Services, LLC, as signed by its authorized representative:

Signature
Print Name
Title
Date

Address to be used for giving notice to UMVS under this Agreement

Street: 2222 W. Dunlap Ave.

City: Phoenix

State: AZ Zip Code: 85021

Liability Insurance Requirements Table – TRICARE West Ancillary

State	UHG Recommended Professional Liability Limits	UHG Minimum Professional Liability Limits	Minimum General Liability Requirements
Standard Specified Professional and General Liability Limits			
Alaska, Arizona, California, Colorado, Hawaii, Idaho, Iowa, Kansas, Minnesota, Missouri, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming	$1,000,000 each claim/ $3,000,000 aggregate	$500,000 each claim/ $1,000,000 aggregate	$1,000,000 per occurrence
Texas	$1,000,000 each claim/ $3,000,000 aggregate	$200,000 each claim and aggregate	$200,000 per occurrence
	$1,000,000 each claim/ $3,000,000 aggregate	TX Comprehensive Rehabilitation Program $500,000 each claim/ $1,000,000 aggregate	$1,000,000 per occurrence

List of Attachments

x	**Payment Appendix**
x	**Provider Liability Insurance Requirements Table**
x	**Provider Demographic Form**

NOTICE PROVISION ADDENDUM TO THE ANCILLARY FACILITY PARTICIPATION AGREEMENT FOR TRICARE PROGRAM

All notices and communications provided by UMVS to Provider under the Ancillary Facility Participation Agreement (the "Agreement), including but not limited, to any fee schedule amendments, must be sent to the Provider's Chief Legal Officer at the following address:

CCS Medical
1505 LBJ Freeway Ste. 600
Farmers Branch, TX 75234
Attn: Chief Legal Officer